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The Doctrine of Simultaneous Conception and Reduction to Practice: An Argument for Its Repudiation

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I. Introduction

In this paper, I argue that the doctrine of simultaneous conception and reduction to practice should be repudiated. Among the numerous reasons for repudiating the doctrine of simultaneous conception and reduction to practice are the following:

(1) it favors the large inventor and is inconsistent with the policy of protecting the small inventor;

(2) it is inconsistent with the policy of encouraging innovation;

(3) it is inconsistent with the preference for uniform patenting rules across all technology types; and

(4) it is an improper attempt to use the patenting system to protect the public although the patent laws do not provide the authority to do so.

II. Background

A. Interferences

A discussion of the doctrine of simultaneous conception and reduction to practice requires an understanding of several statutory provisions in the patent laws.[2]

1. Constitutional Basis

The Constitutional grant of power to Congress to enact the patent laws states, "The Congress shall have the power…[t]o promote the Progress of Science and useful Arts, by securing for limited Times to…Inventors the exclusive Right to their…Discoveries…"[3]

The United States is virtually the only country in the world that grants rights to the first "inventor," rather than the first to file a patent application[4] with the relevant patenting authority.[5] The grant of right is in the form of a patent[6] issued by the United States Patent and Trademark Office (USPTO).[7] While several parties may independently arrive at the same invention, only the party that is first to invent it is entitled to exclusive patent rights.[8] The issue of determining the first inventor is also referred to as the issue of priority of invention.[9] The statutory basis for the requirement for priority of invention states:

> A person shall be entitled to a patent unless-…(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.[10]

Section 135 authorizes the Commissioner to declare an "interference," which is an *inter partes* proceeding, whenever an application for patent is believed to interfere with any pending application or any unexpired patent.[11] It mandates that the Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability.[12] It further states that the Commissioner may issue a patent to the applicant who is adjudged the prior inventor.[13] Section 291 provides that an owner of an interfering patent may have relief against the owner of another patent by civil action.[14] That is, the USPTO does not have jurisdiction over interferences involving

only patents and not involving any pending applications.[15] Section 104 permits establishment of a date of invention by reference to activity in a NAFTA country or a WTO member country.[16]

Several strong arguments exist in favor of adopting a first-to-file system, thereby replacing the current first-to-invent system.[17] One argument is that interference proceedings are costly and lengthy;[18] as a general rule, the prevailing party in an interference proceeding is usually the party that was first to file. [19]

2. Priority

Thus, a determination of priority of invention requires findings regarding conception, reduction to practice, and diligence.

a. Conception

A definition of conception was formulated in the leading case of *Mergenthaler v. Scudder*.[20] According to the *Mergenthaler* standard, complete conception is "the complete performance of the mental part of the inventive act…[i]t is, therefore, the formation in the mind of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice..."[21] The Board of Patent Interferences has further stated that "conception is established when the invention is made sufficiently clear to enable one skilled in the art to reduce it to practice without the exercise of extensive experimentation or the exercise of inventive skill."[22]

The inventor must recognize and appreciate the invention in order to establish conception.[23] However, conception does not require that the inventor know that the invention will work.[24]

b. Reduction to Practice

Two types of reduction to practice exist, and either can be used to determine priority of invention: an actual reduction to practice or a constructive reduction to practice.[25] To establish an actual reduction to practice in an interference proceeding, a party must prove that "(1) the party constructed an embodiment or performed a process that met every element of the interference count,[26] and (2) that the embodiment or process operated for its intended purpose."[27] Establishing actual reduction to practice requires a showing that the invention was manifested in a physical or tangible form, which includes every element of the count.[28]

Furthermore, the invention must have been tested to an extent sufficient to show that it will work for its desired purpose.[29] The type of testing that must have been performed depends upon the nature of the invention and the facts of the case.[30] An invention is not actually reduced to practice unless the utility of the invention is known at the time of the reduction to practice.[31]

The Supreme Court in *Corona v. Dovan*[32] articulated the requirement of reduction to practice for each category[33] of patentable invention:

> A process is reduced to practice when it is successfully performed. A machine is reduced to practice when it is assembled, adjusted and used. A manufacture is reduced to practice when it is completely manufactured. A composition of matter is reduced to practice when it is completely composed.[34]

A constructive reduction to practice occurs when a patent application meeting the statutory disclosure requirements[35] is filed with the USPTO.[36]

c. Diligence

The first party to reduce an invention to practice is the first inventor, unless the other party was the first to conceive and exercised diligence from a time just prior to when the later conceiver entered the field, and the diligence continued to the first conceiver's reduction to practice.[37] A party relying on the diligence scenario must show affirmative acts or acceptable excuses for not acting throughout the entire period during which diligence is required.[38]

d. Priority Distinguished from Originality

Originality, like priority, also focuses on inventorship.[39] However, originality addresses who actually invented the subject matter, whereas priority addresses who invented first.[40]

B. Patentability

Appreciation of the analysis of the case law, which is relevant to the doctrine of simultaneous conception and reduction to practice, further requires an understanding of the process by which an inventor obtains a patent.

1. Statutory Authority

To obtain a patent, an applicant for patent must file with the USPTO a patent application that meets the utility,[41] novelty,[42] nonobviousness,[43] and enablement[44] requirements of the Patent Statute. It must further satisfy the statutory requirements of providing a written description,[45] best mode,[46] and one or more claims.[47] The patentability determination is made in an *ex partes* proceeding before a patent examiner of the USPTO.

a. Utility

The Patent Statute imposes a utility requirement on the applicant for patent.[48] Section 101 provides:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.[49]

The federal courts have interpreted Section 101 of the Patent Statute to have two purposes: (1) it defines the categories of inventions for which patent protection can be obtained, and (2) it requires that patented inventions be "useful."[50] If the invention does not comprise a machine, a process, an article of manufacture, or a composition of matter, it is not eligible for patent protection.[51] Categories of inventions that are not patentable on the ground of lack of utility include inoperative or fraudulent inventions, as well as inventions that are against public policy.[52] An "inoperative" invention is one that does not operate to produce the results claimed by the applicant.[53] Other subject matter that is not patentable includes: printed matter,[54] a naturally occurring article,[55] and a scientific

principle.[56] The Court of Appeals for the Federal Circuit (CAFC) [57] has stated that "[t]o violate [35 U.S.C.] 101 the claimed[58] device must be totally incapable of achieving a useful result."[59]

A further limitation on patentable subject matter is imposed by the Atomic Energy Act of 1954.[60] The Atomic Energy Act states that a patent cannot be granted on an invention the utility of which lies solely in its use as an atomic weapon.[61]

b. Novelty

The Patent Statute further requires that an invention be "novel" and that none of the subsections of Section 102 operate to preclude the grant of a patent.[62] Section 102 is the most frequently litigated, and arguably most important, section of the Patent Statute.[63] In the past 150 years, each word in Section 102 has been construed in thousands of cases.[64] The principle underlying each of the subsections of Section 102 is that an inventor may only obtain the exclusionary property right, which is granted by a patent, if the invention is not within the public domain.[65]

Section 102 provides, in part:

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use of on sale in this country, more than one year prior to the date of the application for patent in the United States, or
> (c) he has abandoned the invention, or
> (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or

inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented…[66]

Compliance with Section 102 of the Patent Statute requires that the claimed subject matter be compared with what is known in the prior art.[67] If there is no difference between the claimed invention and the prior art, the claimed invention does not satisfy the novelty requirement.[68] If differences are found between the claimed invention and the prior art, it must then be determined whether the invention would have been obvious at the time it was made.[69]

Section 102 implicitly defines the "prior art references," upon which a patent examiner can rely to reject the patent applicant's claimed invention.[70] A prior art reference can be a United States patent, a foreign patent, or a technical or scientific article or publication.[71]

Thus, Section 102 bars issuance of a patent if the prior art "anticipates" or is identical to the invention.[72] Section 102 requires that a single prior art reference disclose every element of the claimed invention.[73]

Each subsection of Section 102 sets forth an operative point in time and a group of persons whose conduct is pertinent.[74] For example, for the purposes of subsection (a), the important point in time is the date of invention by the applicant, whereas, for the purposes of subsection (b), the important point in time is the date one year prior to the date of filing for patent in the United States.[75] Furthermore, subsection (a) refers to

knowledge or use "by others," whereas subsection (b) applies to both the conduct of others and conduct by the inventor herself.[76]

The implicit and inherent disclosures or a prior art reference, as well as the express disclosures thereof, may be used in the patent examiner's rejections of claims under Section 102 of the Patent Statute.[77] Rejections based upon inherent disclosures are commonly termed "inherency rejections."[78]

Subsection (f) of Section 102 defines the "derivation" scenario.[79] If an applicant did not invent the subject matter sought to be patented, it is said to be an invention derived from another.[80]

c. Nonobviousness

After the patent applicant overcomes the hurdles of Section 102 of the Patent Statute, the applicant must also satisfy the requirement under Section 103, that the claimed invention as a whole be nonobvious to a person of ordinary skill in the art at the time the invention was made.[81] Section 103 provides, in part:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[82]

In *Graham v. John Deere*,[83] the Supreme Court set forth four factual determinations that must be made during the nonobviousness inquiry.[84] First, the scope and content of the prior art must be ascertained.[85] Second, the differences between the claims and the prior art must be determined.[86] Third, the level of ordinary skill in the pertinent art must

be resolved.[87] Fourth, secondary considerations—such as commercial success, licensing, failure of others, unexpected results, copying by others, skepticism of experts, and long felt, but unsolved needs—may be relevant as indicia of nonobviousness.[88]

In the application of the *Graham* standard, several other tenets of patent law are also followed:

(1) The claimed invention is considered as a whole;

(2) The references are considered as a whole, and they must suggest the desirability of combining the references in the manner required to arrive at the claimed invention;

(3) The references must not be viewed with the benefit of hindsight provided by the claimed invention; and

(4) Obviousness is determined using the standard of a reasonable expectation of success.[89]

To make a rejection under Section 103, the patent examiner relies upon references defined by Section 102.[90] As required in a rejection under Section 102, all the claim limitations or elements of the invention must be taught or suggested by the prior art to establish obviousness.[91] However, in contrast to a rejection under Section 102, all the limitations need not be taught in a single reference.[92]

The final sentence of Section 103 makes irrelevant to patentability whether or not the invention was a result of a flash of genius.[93] Thus, the fact that an invention resulted from years of painstaking experimentation has no bearing on the nonobviousness determination.[94]

d. Written Description

The next three requirements for patentability are set forth in the following language from the Patent Statute:

> 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.[95]

Section 112, first paragraph, requires that the specification of the patent application include a written description of the invention, enablement or disclosure of the manner and process of making and using the invention, and disclosure of a best mode for carrying out the invention as contemplated by the inventor.[96] These three requirements are separate and distinct from each other.[97] The policy underlying Section 112, first paragraph, is to ensure that the public receives an adequate disclosure of the invention in exchange for the exclusionary, monopolistic rights granted to the inventor.[98]

The standard applied to determine the adequacy of the written description is: "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed."[99] The issue of compliance with the written description requirement is generally raised when there is a question as to whether the subject matter of a claim[100] is supported by the written description as of the filing date of the application for patent.[101] Since claims included in the original patent application constitute their own description,[102] the issue arises when the original claims are subsequently amended or new claims are subsequently added.[103] The question then is whether the amended and/or new claims are supported by the description.[104]

The written description requirement is relevant in *inter partes* interference proceedings, as well as *ex parte* patentability determinations.[105] That is, a claim corresponding to a count is also required to be supported by the specification under Section 112, first paragraph.[106]

e. Enablement

The second requirement set forth in Section 112, first paragraph, is that of enablement; that is, the disclosure must enable one skilled in the art to make and use the claimed invention.[107] The entire scope of the claimed invention must be enabled.[108] The following example illustrates a scenario in which the enablement requirement is met, but the written description requirement is not. One may consider a situation wherein, subsequent to filing, the applicant adds a claim limitation that is not described in the original disclosure (does not meet written description requirement), yet the statement of the new limitation is capable, in and of itself, of teaching one skilled in the art how to make and use it (does meet enablement requirement).[109]

The standard for determining compliance with the enablement requirement is whether the claimed invention has been enabled such that a person of ordinary skill in the art can make and use it without resorting to undue experimentation.[110] Many factors can be addressed to assist in the determination of whether experimentation is undue.[111] These factors include considerations such as the level of ordinary skill in the art, the level of predictability in the art, and the nature of the invention.[112] However, the patent disclosure preferably does not disclose what is well known in the relevant art.[113]

f. Best Mode

The final requirement of Section 112, first paragraph, is the best mode requirement.[114] Essentially, this requirement prohibits inventors from retaining for themselves the best way of carrying out their invention, while only disclosing their second-best embodiments.[115] However, if the inventor discloses several embodiments, he is not required to explicitly identify which of the embodiments comprises the best mode contemplated by him.[116]

g. Claim(s)

The final requirement for patentability is set forth in Section 112, second paragraph, of the Patent Statute, as follows:

> 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.[117]

Section 112, second paragraph, requires that the applicant for patent include one or more claims that define the metes and bounds of the invention.[118] The claims can be rejected under this section for indefiniteness. It is a fundamental principle in the patent law that Section 112, second paragraph, permits an applicant for patent to be his own lexicographer, defining his invention using terms of his choice, [119] as long as they are not used in a manner repugnant to their accepted meaning.[120]

2. Priority Concepts in Patentability: Swearing Back of a Reference

The issues of conception, reduction to practice, and diligence are most commonly applied to interference matters,[121] but they may also arise in other contexts, such as

during the determination of patentability.[122] In general, an applicant for patent need not submit the dates of actual conception or actual reduction to practice to obtain a filing date or to obtain a patent.[123] Rather, the date of filing the patent application serves as the conception date and date of constructive reduction to practice.[124]

During the patentability proceedings, the USPTO may find prior art references that establish lack of novelty or lack of nonobviousness.[125] The applicant may, if the facts allow, choose to respond to such rejections of its claims by swearing behind one or more of the references relied upon by the USPTO.[126] Swearing behind a reference entails showing in a "131 affidavit or declaration" that the applicant invented prior to the effective date of the reference relied upon in the rejection.[127] If the applicant succeeds in showing invention prior to the effective date, he overcomes the prior art rejection.[128] For the most part, the terms "conception," "reasonable diligence," and "reduction to practice" have the same meanings under 37 C.F.R. §1.131 as they have in interference proceedings.[129]

III. Emergence of the Doctrine of Simultaneous Conception and Reduction to Practice and Its Application by the Courts

A. Emergence of the Doctrine

In his treatise of 1890, Professor Robinson first set forth the notion that in some instances conception cannot be separated from reduction to practice:

> In many inventions the act of conception is clearly distinct, in point of time, from that of reduction (and the definite and permanent idea standard can be applied)… In many others the work of conception and reduction goes forward almost simultaneously, so nearly that no date can be fixed as that before which the conception was complete and after which the reduction to practice was begun. This is true in nearly all inventions

> which are the result of experiment, --where the inventor, instead of evolving the entire art or instrument out of his own thought, conjectures that such an act or substance will subserve a given purpose, and having tried it, finds that it accomplishes the end…at no instant before the experiment succeeds can it be said that the conception of the invention exists in the inventor's mind…the first to bring the art or instrument into successful operation is the first conceiver of the entire invention.[130]

B. Case Law

Since Professor Robinson's exposition on the doctrine of simultaneous conception and reduction to practice, the Court of Appeals for the Federal Circuit has questioned the doctrine's basis but has not repudiated it.[131]

1. Smith v. Bousquet

Fifty years after Professor Robinson defined the doctrine, the Court of Customs and Patent Appeals[132] (CCPA) first enunciated, in *Smith v. Bousquet*,[133] the view that the doctrine of simultaneous conception and reduction to practice applies as a rule of law to inventions within disciplines that are "inherently unpredictable."[134] According to the *Bousquet* court, inherently unpredictable disciplines include the chemical and biological sciences.[135]

In *Bousquet*, the appellant was the senior party[136] in an interference, and the appellee was the junior party.[137] The appellant sought review of a decision by the appeals board of the USPTO, which affirmed the examiner's award of priority of the invention to the appellee.[138]

At issue in *Bousquet* were two counts[139] to an insecticide.[140] The court noted that the utility of a particular material as an insecticide must be determined by testing under

conditions of intended use.[141] The court based its imposition of this requirement on the facts that, among other things, insects vary widely in their susceptibility to a given toxic substance and that the mode of application depends upon the type of insect and the environment in which it is found.[142] Furthermore, the court noted that a relationship between chemical structure and utility as an insecticide is not known, and, therefore, it is impossible to predict, given only the chemical structure, whether or not a compound will be useful as an insecticide.[143] The court utilized the *Mergenthaler* standard that "[it] is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice that constitutes an available conception within the meaning of the patent law."[144] Applying this standard to the facts, the *Bousquet* court held that the conception date was the date upon which test results verified that the insecticide was toxic to mosquito larvae.[145]

2. Alpert v. Slatin

Even though the *Bousquet* decision opened the door for the CCPA to apply the doctrine of simultaneous conception and reduction to practice, it did not do so for 22 years.[146] In *Alpert v. Slatin*,[147] which was decided in 1962, the CCPA affirmed a decision of the Board of Patent Interferences (the "Board") that the priority decision is essentially a factual determination.[148] The issue in Alpert was the priority of invention of a process defined in a single count for producing titanium metal.[149] The *Alpert* court affirmed the Board's decision to award priority to the senior party Slatin.[150]

The *Alpert* Court stated that the junior party Alpert had the burden of proving priority of invention and failed to meet that burden.[151] Party Alpert proffered evidence of his

conception, which showed "adoption of a program of exploration of the possibility of depositing titanium by some electrolytic procedure from a titanium salt of lower valence than a quadrivalent."[152] The *Alpert* Court agreed with the Board's opinion that this evidence was based on theoretical, thermodynamic considerations and that it merely recommended that the depositions be tried.[153]

The *Alpert* Court applied the *Mergenthaler* standard of conception, which provides that the inventor must have "mental possession of the steps of an operative process and, if necessary, of means to carry it out to such a degree that nothing remains but routine skill for effectuation thereof."[154] The court stated that if, on a given date, extensive research was still necessary before arriving at minimum satisfactory performance, the mental possession on that date was a mere hope or expectation, not conception.[155] The *Alpert* Court suggests that a determination of whether or not to apply the doctrine of simultaneous conception and reduction to practice can be made by assessing the nature of the research.[156]

Applying this definition of conception, the *Alpert* Court found that the evidence proffered by junior party Alpert did not show conception.[157] The Court reasoned that, subsequent to the date of Alpert's evidence, extensive research was required, and such research was characterized by perplexing difficulties every step of the way.[158]

3. In re Seaborg

Two years after *Alpert*, the CCPA once more recognized the doctrine of simultaneous conception and reduction to practice.[159] The invention at issue in *In re Seaborg*[160] comprised the chemical element Americium.[161] The examiner had rejected the

application on the basis of a prior art reference (the Fermi patent[162]), which disclosed several nuclear reactors and methods for their operation.[163] The *Seaborg* Court found that the character of the element and the process by which it was made were both unpredictable and held that the doctrine of simultaneous conception and reduction to practice applied to an invention of this kind.[164] Specifically, the properties of the element or the exact procedures to be followed to make it could not be predicted without exercising more than ordinary skill in the art.[165] Therefore, conception could not exist until the experiments were actually performed for producing detectable amounts of the invention, and the method disclosed in the prior art reference did not produce detectable amounts.[166]

Taken together, the *Bousquet*, *Alpert*, and *Seaborg* decisions could be construed as the firm adoption by the CCPA of the doctrine of simultaneous conception and reduction to practice. However, subsequent decisions indicate the CCPA's actual lack of confidence in the doctrine.

4. Applegate v. Scherer

For example, in *Applegate v. Scherer*, [167] the Court failed to apply the doctrine of simultaneous conception and reduction to practice[168] under facts of a chemical, the invention of which required extensive experimentation.[169] In *Applegate*, junior party Scherer and senior party-appellants Applegate had filed patent applications claiming a method for controlling sea lampreys with a nitrophenol compound.[170] The sole issue in the case was originality, or whether one party had derived the invention from the other party.[171] Scherer had written to Applegate requesting that Applegate conduct tests with

the chemical to assess its efficacy in the control of sea lamprey.[172] Applegate argued that it could not have derived the invention from Scherer based upon this disclosure because, in effect, there was no invention to derive.[173] In other words, the doctrine of simultaneous conception and reduction to practice applied, and, therefore, until successful testing was performed, conception did not exist.[174]

Without addressing the logic of Applegate's argument, the *Applegate* Court proceeded to distinguish the facts from those in *Bousquet* and *Alpert* on the basis that these prior cases did not involve the issue of originality.[175] It further distinguished the case from *Bousquet* by stating that the facts before the Court did not involve facts of the type in *Bousquet*.[176] However, this was clearly an erroneous characterization of the facts.[177]

5. Rey-Bellet v. Engelhardt

The CCPA further eroded the doctrine of simultaneous conception and reduction to practice in the case of *Rey-Bellet v. Engelhardt* .[178] *Rey-Bellet* involved a three party interference, wherein Schindler was the senior party.[179] The Board of Patent Interferences had held that junior parties Rey-Bellet and Engelhardt each failed to prove dates of invention that were prior to Schindler's date of invention.[180] The *Rey-Bellet* Court reversed, holding that Engelhardt be awarded priority.[181] Engelhardt had prepared the claimed chemical, which was referred to as "NTL," prior to the date of Schindler's invention; however, reduction to practice was disputed because it was unclear whether a practical utility[182] had been established.[183] Although Engelhardt had not performed testing in humans, he argued that he had conceived the utility of antidepressant activity

on the basis that the chemical structure of NTL was very similar to that of amitriptyline, which was known to possess antidepressant activity in humans.[184] Relying upon *Alpert*, Schindler argued that Engelhardt's basis for utility at most indicated a mere hope that NTL would act as an antidepressant, and, therefore, Engelhardt had failed to show reduction to practice.[185] The *Engelhardt* Court rejected this argument, stating that the tests, which would be performed to show definitively an antidepressant activity in humans, posed no perplexing intricate difficulties and involved only the exercise of routine skill in the art.[186]

6. Oka v. Youssefyeh

In *Oka v. Youssefyeh*,[187] the CAFC appeared to open the door to the doctrine of simultaneous conception and reduction to practice, although the court did not expressly apply the doctrine.[188] In *Oka*, the Patent Office Board of Patent Appeals and Interferences had awarded priority to junior party Youssefyeh, and the court reversed.[189] The count to the interference was directed to a chemical compound, which was useful for inhibiting the activity of a particular enzyme.[190] Citing *Alpert* and other cases, the *Oka* Court applied the rule that conception of a chemical compound requires an idea of the structure thereof and possession of a method of making it.[191]

7. Amgen, Inc. v. Chugai Pharmaceutical Co.

In the pair of cases that were decided subsequent to *Oka*, the CAFC adopted the doctrine of simultaneous conception and reduction to practice in the context of inventions for genetic material.[192] However, the most recent pronouncement by the CAFC has expressly declined to extend the doctrine beyond these facts.[193]

In 1991, the CAFC added biotechnology to the list of disciplines that are inherently unpredictable.[194] The claimed invention in *Amgen* was a gene that encoded a protein (erythropoietin), which is useful for stimulating the production of red blood cells and is therefore useful in the treatment of anemia.[195] Noting that a gene is merely a complex chemical compound and citing *Oka*, the *Amgen* Court applied the definition for conception of a chemical compound, which was applied by the *Oka* Court.[196] The *Amgen* Court, unlike the *Oka* Court, expressly applied the doctrine of simultaneous conception and reduction to practice.[197] The *Amgen* Court held that, in the context of an invention directed to a gene, invention requires reduction to practice, and reduction to practice requires isolation of the gene.[198]

8. Fiers v. Revel

In the subsequent case of *Fiers v. Revel*,[199] the CAFC once again applied the doctrine of simultaneous conception and reduction to practice,[200] but the facts were not expanded appreciably beyond those of *Amgen*. The invention in *Fiers* was also directed to a gene, which encoded a protein (human fibroblast beta-interferon) useful for promoting viral resistance in humans.[201] In apparent contradiction with the holding of *Rey-Bellet*, which held that conception can be complete if subsequent, confirming tests are straightforward and routine, the *Fiers* Court held that conception of a gene required its isolation, even if such isolation may be characterized as routine and simple.[202]

9. Burroughs Welcome Co. v. Barr Laboratories, Inc.

In *Burroughs Welcome Co. v. Barr Laboratories, Inc.*,[203] the CAFC applied the *Mergenthaler* standard for conception[204] and rejected the proposition that the doctrine of simultaneous conception and reduction to practice as a general rule must be applied to unpredictable areas of technology.[205] The claimed invention in *Burroughs Welcome* was directed to the preparation of the drug AZT and methods of using AZT for the treatment of human immunodeficiency virus (HIV).[206] Applying only the *Mergenthaler* standard of conception, the *Burroughs Welcome* Court held that Burroughs Welcome scientists had completely conceived the invention before tests, which showed the efficacy of AZT in humans, were performed by others.[207] The *Burroughs Welcome* Court further stated that "an inventor need not know that his invention will work for conception to be complete."[208]

IV. Arguments for the Repudiation of the Doctrine of Simultaneous Conception and Reduction to Practice

As the review of the case law suggests, the doctrine of simultaneous conception and reduction to practice has not been embraced by the courts. The courts certainly have not applied the doctrine in the manner contemplated by Professor Robinson, who suggested uniform application to "nearly all inventions which are the result of experiment."[209]

There are several bases upon which the CAFC could take the next, short step and repudiate this questionable doctrine.

A. No Statutory Requirement for Simultaneous Conception and Reduction to Practice

The Patent Statute does not contain a requirement for simultaneous conception and reduction to practice for any type of invention. If Congress determines that inventions in certain technological areas cannot be conceived at a date distinct from the date of reduction to practice, it can change the Patent Statute accordingly.

B. Improper Attempt to Protect the Public

The imposition of the doctrine of simultaneous conception and reduction to practice appears to be an attempt to protect the public from inventions that may not work. The Patent Statute, however, does not require that the applicant for patent prove the operability of his claimed invention. In *Webber v. Virginia*,[210] the Supreme Court stated, "Congress never intended the patent laws displace the police powers of the state…"[211]

The Patent Statute does not require that an applicant for patent provide a model, exhibit, or specimen of the invention.[212] Furthermore, the C.A.F.C. has stated that "[t]he mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it."[213]

The conflict presented by the doctrine of simultaneous conception and reduction to practice is similar to that which existed when the USPTO attempted to require safety determinations for drug inventions. In addressing this issue, the CCPA stated that it is not the province of the USPTO to determine under the utility requirement[214] whether drugs are safe.[215] The CAFC also recently stated, "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws."[216] In its guidelines for the examination of therapeutic and pharmacological inventions, the USPTO has stated that its review is now confined to the statutory requirements for

patentability.[217] Other governmental agencies are responsible for ensuring conformance to, for example, safety and efficacy standards.[218]

C. Contrary to Policy of Uniform Treatment of All Technologies

Public policy favors the application of uniform patenting standards to the different types of technologies.[219] The doctrine of simultaneous conception and reduction to practice further complicates the already complicated issue of conception.[220] And this complication weighs most heavily upon biotechnological inventions.

D. Chilling Effect on Biotechnological Innovation

Nevertheless, some commentators have argued that courts should apply the doctrine of simultaneous conception and reduction to practice as a general rule to pharmaceutical and chemical science.[221] However, commentators have also recognized that the development of patent law principles, which are particularly stringent with respect to biotechnological inventions, inevitably chills the development of biotechnological innovations.[222] A goal of the patent laws is to encourage, not dissuade, innovation.[223]

E. Disadvantages the Small Inventor

Meeting a reduction to practice requirement necessarily implies access to manpower and equipment and the financial resources to gain that access.[224] Thus, a requirement of simultaneous conception and reduction to practice clearly places the small inventor at a disadvantage over large, corporate inventors that have the requisite resources.[225] Only a little perspicacity is required to predict that, given the increasing importance of

biotechnological inventions, the doctrine of simultaneous conception and reduction to practice will likely be raised in future litigation with increasing frequency. The courts should remain cognizant of the unfairness to small inventors, particularly in light of the fact that large, corporate inventors are also better equipped to litigate and attempt to influence the law.

V. Conclusion

The CAFC should finally repudiate the doctrine of simultaneous conception and reduction to practice. This doctrine only serves to add confusion to an already extremely complicated area of interference law.

Biotechnology is rapidly becoming an influential area of technology, promising much, for example, in the way of treatments for genetically-based diseases. If this doctrine is not repudiated, it will only serve to chill innovation in biotechnology.

Furthermore, the doctrine disadvantages the small inventor. Yet one of the underlying justifications of the interference proceeding itself is to protect the rights of the small inventor, who may not be able to afford to pursue the patent acquisition process as expeditiously as the large inventor. As indicated by the analysis in *Burroughs Welcome*, the *Mergenthaler* standard is an adequate standard for determining conception in the chemical and biological arts. The doctrine of simultaneous conception and reduction to practice only serves to improperly foreclose for the biotechnological inventor reliance upon the diligence scenario to show prior invention. The Patent Statute does not support this selective mistreatment of the biotechnological inventor- neither should the courts.

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[2] *See* Patent Act, 35 U.S.C. §§ 101-103, 112, 135 (2000).

[3] U.S. CONST. art. I, § 8, cl. 8.

[4] *See* 35 U.S.C. § 111 (setting forth the patent application requirements : a written description of the invention, one or more claims defining the invention, one or more drawings (if necessary to explain the invention), an oath or declaration stating that the applicant is the original inventor, and a filing fee).

[5] J. THOMAS MCCARTHY, MCCARTHY'S DESK ENCYCLOPEDIA OF INTELLECTUAL PROPERTY 132 (1991).

[6] *See* 35 U.S.C. §154(stating that every patent shall contain a grant of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process. The term is for 20 years from the date of filing of the patent application).

[7] *See* BLACK'S LAW DICTIONARY 778-79 (6th ed. 1990) (stating the USPTO is a federal agency in the Department of Commerce headed by the Commissioner of Patents and Trademarks. Among other things, the USPTO examines patent and trademark applications, issues patents, registers trademarks, records documents transferring ownership, maintains a scientific library and search files, hears and decides appeals from applicants for patents and trademarks, and maintains a roster of persons registered to practice before the USPTO).

[8] *See* 35 U.S.C. §102(g).

[9] *See id.* § 135.

[10] *Id.* §102(g).

[11] *See id.* §135.

[12] *See id.* (stating an application for patent may mature to a patent if it satisfies the patentability requirements set forth in 35 U.S.C. §§ 101-103 and 112). *See discussion infra* Part II.B.1.a-g.

[13] *See* 35 U.S.C. §135.

[14] *See id.* § 291.

[15] *See* U.S. DEPARTMENT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2300.01 (7th ed. rev. 1 2000) [hereinafter M.P.E.P.].

[16] *See* 35 U.S.C. § 104.

[17] *See* Donald R. Dunner, *First to File: Should Our Interference System Be Abolished?*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 561 (1986).

[18] *See id*. at 563.

[19] *See id*.

[20] Mergenthaler v. Scudder, 11 App. D.C. 264, 276 (D.C. Cir. 1897).

[21] *Id.*

[22] Hiatt v. Ziegler, 179 U.S.P.Q. 757, 763 (Bd. Pat. App. & Inter. 1973).

[23] *See* Silvestri v. Grant, 496 F.2d 593, 596 (C.C.P.A. 1974) (holding that "an accidental and unappreciated duplication of an invention does not defeat the patent right of one who, though later in time, was the first to recognize that which constitutes the inventive subject matter").

[24] *See* Burroughs Welcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) (finding that patent application describing treatment of AIDS with AZT and disclosing dosages, forms, and routes of administration was adequate to collaborate conception regardless of whether the inventors believed on the basis of initial screening tests that the invention would work).

[25] *See* M.P.E.P., *supra* note 14, § 2138.05.

[26] *See* Patent Rules, 37 C.F.R. § 1.601 (2000) (stating that a "count" sets forth the interfering subject matter and is worded like a claim. The claims involved in an interference proceeding are said to "correspond to the count." Each claim may correspond exactly (claim is identical to the count) or correspond substantially (claim is not identical to the count).

[27] Eaton v. Evans, 204 F.3d 1094, 1097 (Fed. Cir. 2000).

[28] *See* Wetmore v. Quick, 536 F.2d 937, 942 (C.C.P.A. 1976).

[29] *See* King Instrument Corp. v. Otari Corp., 767 F.2d 853, 860 (Fed. Cir. 1985).

[30] *See* Gellert v. Wanberg, 495 F.2d 779, 783 (C.C.P.A. 1974) (holding that "an invention may be tested sufficiently … where less than all of the conditions of actual use are duplicated by the tests").

[31] *See* Wiesner v. Weigert, 666 F.2d 582, 588 (C.C.P.A. 1981).

[32] Corona v. Dovan, 273 U.S. 692 (1928).

[33] *See discussion infra* Part II.B.1.a (regarding categories of patentable inventions defined by the patent statute).

[34] Corona, 276 U.S. at 358, 383.

[35] *See infra* Part II.B.1.d-f.

[36] *See* M.P.E.P., *supra* note 14, § 2138.05.

[37] *See* Hull v. Davenport, 90 F.2d 103, 105 (C.C.P.A. 1937).

[38] *See, e.g.*, Griffith v. Kanamaru, 816 F.2d 624 (Fed. Cir. 1987) (holding that lack of university funding and personnel do not qualify as acceptable excuses).

[39] *See* Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993).

[40] *See id*.

[41] *See* Patent Act, 35 U.S.C. § 101 (2000).

[42] *See id.* § 102.

[43] *See id.* § 103.

[44] *See id.* § 112 para. 1.

[45] *See id.*

[46] *See id.*

[47] *See id.* para. 2.

[48] *See id.* § 101.

[49] *Id.*

[50] *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1981); Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).

[51] *See* 35 U.S.C. § 101.

[52] *See* M.P.E.P., *supra* note 14, § 706.03(a).

[53] *See, e.g.*, Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989); *In re* Harwood, 390 F.2d 985, 989 (C.C.P.A. 1968).

[54] *See In re* Miller, 418 F.2d 1392, 1396 (C.C.P.A. 1969).

[55] *See Ex parte* Grayson, 51 U.S.P.Q. 413, 413 (Bd. App. 1941).

[56] *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 83 (1854).

[57] *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982); *see infra* note 131 (The CAFC is an Article III court, which merges the former Court of Customs and Patent Appeals (CCPA) and the Court of Claims); *See* South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (The CAFC adopted as its own the precedents of the CCPA and the Court of Claims.); *See* Judiciary and Judicial Procedure Act, 28 U.S.C. § 1295 (2000) (The CAFC has exclusive jurisdiction over appeals from district court decisions in patent cases. A party can also appeal directly to the CAFC a decision by the Board of Patent Appeals and Interferences of the USPTO.); *See* Patent Act, 35 U.S.C. §§ 145, 146 (2000) (Alternatively, a party to an interference can sue in federal district court.); *See* 28 U.S.C. § 1295 (If the party chooses the latter course, the CAFC has exclusive jurisdiction over any appeal from the district court proceeding).

[58] *See discussion infra* Part II.B.1.g explaining patent claims.

[59] Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992).

[60] *See* Atomic Energy Act of 1954, 42 U.S.C. § 2181 (2000).

[61] *Id.*

[62] *See* Patent Act, 35 U.S.C. § 102 (2000).

[63] *See* 1 IRVING KAYTON, PATENT PRACTICE 4.1 (6th ed. 1995).

[64] *See id.* at 4.4.

[65] *See id.* at 4.1.

[66] 35 U.S.C. § 102. *See supra* Part II.A.1 for the language of subsection (g).

[67] *See* M.P.E.P., *supra* note 14, § 2106.

[68] *See id.*

[69] *See* 35 U.S.C. § 103. *See infra* Part II.B.1.c for a discussion of the nonobviousness requirement.

[70] *See* 1 KAYTON, *supra* note 62, at 4.1.

[71] *See id.*

[72] *See* 35 U.S.C. § 102.

[73] *See, e.g.*, Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715-16 (Fed. Cir. 1984).

[74] *See* 35 U.S.C. § 102.

[75] *See id.*

[76] *See id.*

[77] *See In re* Napier, 55 F.3d 610, 613 (Fed. Cir. 1995) (affirming a rejection under section 103 on the basis in part of inherent disclosure of a reference. Express, inherent, and implicit disclosures can also be relied upon in rejections under section 103.).

[78] *See* M.P.E.P., *supra* note 14, § 2112.

[79] *See* 35 U.S.C. § 102.

[80] *See* 1 KAYTON, *supra* note 62, at 4.30.

[81] *See* 35 U.S.C. § 103.

[82] *Id.*

[83] Graham v. John Deere, 383 U.S. 1(1966).

[84] *See id.* at 17-18.

[85] *See id.* at 17.

[86] *See id.*

[87] *See id.*

[88] *See id.* at 18.

[89] *See* Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n.5 (Fed. Cir. 1986).

[90] *See* M.P.E.P., *supra* note 14, § 2141.01.

[91] *See In re* Royka, 490 F.2d 981, 985 (C.C.P.A. 1974).

[92] *See* Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991).

[93] *See* Ryko Manufacturing Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991).

[94] *See id.*

[95] Patent Act, 35 U.S.C. § 112 para. 1 (2000).

[96] *See id.*

[97] *See In re* Barker, 559 F.2d 588, 591 (C.C.P.A. 1977) (stating that the written description requirement is separate and distinct from the enablement requirement); *In re* Newton, 414 F.2d 1400, 1406 (C.C.P.A. 1969) (stating that the best mode requirement is separate and distinct from the enablement requirement).

[98] *See* M.P.E.P., *supra* note 14, § 2162.

[99] *In re* Gosteli, 872 F.2d 1008, 1012 (Fed. Cir. 1989).

[100] *See discussion infra* Part II.B.1.g.

[101] *See* Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563- 64 (Fed. Cir. 1991).

[102] *See In re* Koller, 613 F.2d 819, 823 (C.C.P.A. 1980).

[103] *See In re* Wright, 866 F.2d 422, 424 (Fed. Cir. 1989).

[104] *See id.*

[105] *See, e.g.,* Fields v. Conover, 443 F.2d 1386, 1391 (C.C.P.A. 1971).

[106] *See id.*

[107] *See*, 35 U.S.C. § 112 para. 1 (2000).

[108] *See In re* Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[109] *See* M.P.E.P., *supra* note 14, § 2164.

[110] *See* Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[111] *See* In re *Wands*, 858 F.2d at 737.

[112] *See id.*

[113] *See In re* Buchner, 929 F.2d 660, 661 (Fed. Cir. 1991).

[114] *See* 35 U.S.C. § 112 para. 1 (2000).

[115] *See In re* Nelson, 280 F.2d 172, 184 (C.C.P.A. 1960).

[116] *See* Ernsthausen v. Nakayama, 1 U.S.P.Q.2d 1539, 1549 (Bd. Pat. App. & Inter. 1985).

[117] 35 U.S.C. § 112 para. 2.

[118] *See id.*

[119] *See In re* Swinehart, 439 F.2d 210, 213 (C.C.P.A. 1971).

[120] *See In re* Hill, 161 F.2d 367, 369 (C.C.P.A. 1947).

[121] *See supra* Part II.A.2.a-c.

[122] *See* New Idea Farm Equip. Corp. v. Sperry Corp., 916 F.2d 1561, 1565 (Fed. Cir. 1990).

[123] *See* Hyatt v. Boone, 146 F.3d 1348, 1352 (Fed. Cir. 1998).

[124] *See* M.P.E.P., *supra* note 14, § 2138.05.

[125] *See supra* Part II.B.1.b-c.

[126] *See* Patent Rules, 37 C.F.R. § 1.131 (2000).

[127] *See* M.P.E.P., *supra* note 14, § 715.01.

[128] *See id.*

[129] *See id.* § 715.07; *cf*. *In re* Eickmeyer, 602 F.2d 974, 978 (C.C.P.A. 1979) (stating that "the purpose of filing a 131 affidavit is not to demonstrate prior invention, per se, but merely to antedate the effective date of the reference" (citing *In re* Moore, 444 F.2d 572 (C.C.P.A. 1971))).

[130] WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 381 (1890).

[131] *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS, §10.04 (2000) (citing Rey-Bellet v. Englehardt, 493 F.2d 1380 (C.C.P.A. 1974)).

[132] *See* BLACK'S LAW DICTIONARY 268 (6th ed. 1990). (The Court of Customs and Patent Appeals (CCPA) is the predecessor of the United States Court of Appeals for the Federal Circuit (CAFC). The CCPA was established in 1929 under Article III of the United States Constitution and was abolished in 1982 by the Federal Courts Improvement Act.).

[133] 111 F.2d 157 (C.C.P.A. 1940).

[134] *See* Smith v. Bousquet, 111 F.2d 157, 158 (C.C.P.A. 1940).

[135] *See id*.

[136] *See* 6 KAYTON, *supra* note 62, at 24.9. (stating the position of the senior party to an interference proceeding is analogous to that of a defendant in ordinary civil litigation, and

the position of a junior party is analogous to that of a plaintiff in that it has the burden of going forward to prove its case.).

[137] *See Bousquet*, 111 F.2d at 158.

[138] *See id.* at 157.

[139] *See supra* note 25 (defining a "count.").

[140] *See Bousquet*, 111 F.2d at 158.

[141] *See id*. at 159.

[142] *See id*.

[143] *See id*. at 160.

[144] *See id* at 159.

[145] *See id*.

[146] *See* Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962).

[147] *Id.*

[148] *Id.*

[149] *See id.*

[150] *See id.* at 897.

[151] *See id.* at 892.

[152] *Id.* at 894 (quoting the Board of Patent Appeals and Interferences).

[153] *See id.*

[154] *Id.*

[155] *See id.*

[156] *See id.*

[157] *See id.*

[158] *See id.*

[159] *See* In re Seaborg, 328 F.2d 996, 999 (C.C.P.A. 1964).

[160] *Id.*

[161] *See id.*0

[162] U.S. Patent No. 2,708,656 (Issued May 1955).

[163] *See* Seaborg *supra* note 58, at 996-7. (Although the prior art reference did not expressly disclose the element Americium, the examiner argued that the process for using the reactor, which was described in the patent, inherently, *see supra* Part II.B.1.b, produced the Americium.).

[164] *See id*. at 999 (citing Smith v. Bousquet, 111 F.2d 157 (C.C.P.A. 1940)).

[165] *See id*.

[166] *See id*. (Since the court effectively removed the prior art reference in its application of the doctrine of simultaneous conception and reduction to practice, it did not consider appellant's 131 affidavits, *see supra* Part II.B.2, which were submitted to establish invention prior to the effective date of the Fermi patent.).

[167] *See* Applegate v. Scherer, 332 F.2d 571(C.C.P.A. 1964).

[168] *Id.* at 573.

[169] *See id*. at 571 (noting that the efficacious compound was defined only after the examination of thousands of compounds).

[170] *See id*.

[171] *See id*. at 572. *See discussion supra* Part II.A.2.d (regarding originality).

[172] *See Applegate*, 332 F.2d at 572.

[173] *See id.* at 573.

[174] *See id.*

[175] *See id.*

[176] *See id.*

[177] *Cf.* Brown v. University of Cal., 866 F.Supp. 439, 444-45 (N.D. Cal. 1994) (noting that, if given the opportunity, the CAFC would overrule *Applegate*).

[178] Rey-Bellet v. Engelhardt, 493 F.2d 1380 (C.C.P.A. 1974).

[179] *See* Rey-Bellet, 493 F.2d at 1381.

[180] *See id*. at 1382.

[181] *See id.* at 1381.

[182] *See supra* Part II.A.2.b.

[183] *See Rey-Bellet*, 493 F.2d at 1382-83.

[184] *See id*. at 1385.

[185] *See id*. at 1386.

[186] *See id*. at 1387.

[187] 849 F.2d 581 (Fed. Cir. 1988).

[188] *See* Oka v. Youssefyeh, 849 F.2d 581, 584 (Fed. Cir. 1988).

[189] *See id.* at 582.

[190] *See id.; See* MCGRAW-HILL'S DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS 686 (5th ed. 1994). *(*An enzyme is a catalyst that is produced by a cell and enhances the rate of a chemical reaction occurring in the cell (i.e., a biological catalyst). In general, a catalyst is a substance that enhances the rate of a chemical reaction, biological or otherwise, without itself being consumed by the reaction.); *See id*. at 324.

[191] *See Oka*, 849 F.2d at 583.

[192] *See* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

[193] *See* Burroughs Welcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994).

[194] *See* Amgen, 927 F.2d at 1206. (holding that genetically engineered microorganisms are not excluded as unpatentable subject matter by 35 U.S.C. § 101.); *see also,* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)(making the test for patentability for inventions embracing living matter a questions of whether the invention is the result of human intervention.); *See also,* M.P.E.P., *supra* note 14, § 2105.

[195] *See Amgen*, 927 F.2d at 1203.

[196] *See id*. at 1206.

[197] *See id.*

[198] *See id.*

[199] *See* Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).

[200] *See* i*d.* at 1169.

[201] *See id.* at 1166.

[202] *See id*. at 1169.

[203] Burroughs Welcome Co. v. Barr Labs., Inc., 40 F.3d 1223 (Fed. Cir. 1994).

[204] *See id.* at 1227-28.

[205] *See id*. at 1229.

[206] *See id*. at 1225.

[207] *See id*. at 1231.

[208] *Id*. at 1228 (citing Applegate, 332 F.2d at 573.

[209] WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 381 (1890).

[210] Webber v. Virginia, 103 U.S. 344 (1880).

[211] *Id.* at 347-348.

[212] *See* Patent Act, 35 U.S.C. § 114 (2000); *See also* M.P.E.P., *supra* note 14, §608.03. (If operativeness is questioned by the patent examiner, the applicant must establish operativeness to the examiner's satisfaction, but the applicant is free to choose his or her own way of making this showing. The classic example of an invention for which the USPTO would require a model or exhibit is a case involving a perpetual motion machine.).

[213] Gould v. Quigg, 822 F.2d 1074, 1078 (Fed. Cir. 1987) (quoting *In re* Chilowsky, 229 F.2d 457, 461 (C.C.P.A. 1956)); *See* M.P.E.P., *supra* note 14, §2164.02. (A patent can be based on predicted results rather than work actually conducted or results actually achieved. Furthermore, the enablement requirement does not demand that an example be disclosed in the application. If an example is disclosed, it may be a "working example," which is based on work actually conducted, or a "prophetic example," which is based on predicted results.).

[214] *See supra* Part II.B.1.a.

[215] *See In re* Watson, 517 F.2d 465, 474-76 (C.C.P.A. 1975).

[216] *In re* Brana, 51 F.3d 1560, 1567 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994)).

[217] *See* M.P.E.P., *supra* note 14, § 2107.02.

[218] *See id*. (Such standards are established by statutes that regulate the advertisement, use, sale or distribution of drugs.).

[219] *See*, *e.g.*, Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 650 (1998) (arguing that "[u]nique patent law treatment, for biotechnology or any other particular technology, raises concern").

[220] *See* Christian J. Garascia, Note, *Evidence of Conception in U.S. Patent Interference Practice: Proving Who is the First and True Inventor*, 73 U. DET. MERCY L. REV. 717, 718 (1996) (noting that the development of the issue of conception has been taxing for the USPTO and the courts (citing 3 DONALD S. CHISUM, PATENTS § 10.04[1] (1995))).

[221] *See*, *e.g.*, Jackie Hutter, M.S., Note, *A Definite and Permanent Idea? Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law*, 28 J. MARSHALL L. REV. 687 (1995) (arguing that the law's view of conception is a relic of a time when inventions were typically within engineering-related disciplines rather than the empirical sciences and that the doctrine of simultaneous conception and reduction to practice is required for pharmaceutical and chemical inventions).

[222] *See, e.g.*, Mueller, *supra* note 218 at 639. (The author argues that "[t]he Lilly court's imposition of a restricted structure-only rule for DNA claims is another significant departure from prior written description precedent…The better rule would allow biotechnological compounds, like any other inventions, to be described functionally by method of preparation, or in any other manner sufficient to convey that the claimed subject matter was in the inventor's possession as of her filing date.").

[223] *See* 1 ERNEST BAINBRIDGE LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 1:9, at 61 (3d ed. 1984).

[224] *See discussion supra* Part II.A.2.b (regarding actual reduction to practice, the proof of which requires a showing of construction or performance and testing of the invention.).

[225] *See, e.g.*, Mueller, *supra* note 218, at 652 (in discussing the written description requirement, observing that "institutional patent applicants benefiting from greater resources for rapidly sequencing additional species of cDNA once a particular gene has been cloned will be at a decided advantage over independent entities or smaller firms without comparable resources").