/* Patents on living matter and software are a "brave new world." The Manual of Patent Examining Procedure's regulations on the patentability of these new types of inventions follows. */

MANUAL OF PATENT EXAMINING PROCEDURE
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CHAPTER 2100 - Table of Contents

2105 Patentable Subject Matter-- Living Subject Matter [R-6]

The decision of the Supreme Court in Diamond v. Chakrabarty, 206 USPQ 193 (1980) held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision the Office has issued these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the Chakrabarty opinion:

1. "Guided by these cannons of construction, this Court has read the term 'manufacture' in [35 U.S.C.] 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"

2. "In choosing such expansive terms as 'manufacture' and 'composition of matter', modified by the comprehensive 'any', Congress plainly contemplated that the patent laws would be given wide scope."

3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'. V Writings of Thomas Jefferson, at 75-76. See Graham v. John Deere Co., 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified Congress replaced the word 'art' with 'process', but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include any thing under the sun that is made by man'. S. Rep. No. 1979, 82d Cong. 2d Sess., 5 (1952)"

4. "This is not to suggest that [35 U.S.C.] 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."

5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity."

6. "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter a product of human ingenuity 'having a distinctive name, character [and] use'."

7. "Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's microorganism is the result of human ingenuity and research."

8. After reference to Funk Seed & Kalo Co., 333 U.S.127 (1948), "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under [35 U.S.C.] 101."

A review of the Court statements above as well as the whole Chakrabarty opinion reveals:

(1) That the Court did not limit its decision to genetically engineered living organisms,

(2) The Court enunciated a very broad interpretation of manufacture and composition of matter in Section 35 U.S.C. 101

(Note esp. quotes 1, 2, and 3 above),

(3) The Court set forth several tests for weighing whether patentable subject matter under Section 35 U.S.C. 101 is present stating (in Quote 7 above) that:

"The relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions."

The tests set forth by the court are (note especially the italicized portions [designated herein thusly *italic portions*]):
-The laws of nature, physical phenomena and abstract ideas are not patentable subject matter.

-A nonnaturally occurring manufacture or composition of matter a product of human ingenuity having a distinctive name, character, [and] use. is patentable subject matter.

-A new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated $E=mc2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'

-However, the production of articles for use from raw materials prepared by giving to these materials *new forms, qualities, properties, or combinations whether by hand, labor or machinery* (emphasis added) is a manufacture under Section 35 U.S.C. 101. In analyzing the history of the Plant Patent Act of 1930, the Court stated: In enacting the Plant Patent Act, Congress addressed both of these concerns [the belief that plants, even those artificially bred, were products of nature for purposes of the patent law . . . were thought not amenable to the written description]. It explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention. S. Rep. No. 315, 71st Cong. 2d Sess. 6-8 (1930); H.R. Rep. No. 1129. 71st Cong. 2d Sess. 7-9 (1930).

The Office will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in Chakrabarty, e.g., that a nonnaturally occurring manufacture or composition of matter is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed.

The standard of patentability has not and will not be lowered. The requirements of 35 U.S.C. 102 and 35 U.S.C. 103 still apply. The tests outlined above simply mean that a rational basis will be present for any 35 U.S.C.101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see MPEP 608.01(p).

Following this analysis by the Supreme Court of the scope of 35 U.S.C. 101, the Board of Patent Appeals and Interferences has determined that plant subject matter or an animal may be protected under 35 U.S.C. 101. In Ex Parte Hibberd, 227 USPQ 443 (Bd PAI 1985) the Board held that plant subject matter may be the proper subject of a patent under 35 U.S.C. 101 even though such subject matter may be protected under the Plant Patent Act (35 U.S.C. 161 to 35 U.S.C. 164) or the Plant Variety Protection Act (7 U.S.C. 2321 et seq.). In Ex Parte Allen, 2 USPQ2d 1425 (Bd PAI 1987), the Board decided that a polyploid Pacific coast oyster could have been the proper subject of a patent under 35 U.S.C. 101 if all the criteria for patentability were satisfied. Shortly after the Allen decision, the Commissioner of Patents and Trademarks issued a notice (Animals - Patentability, 1077 O.G. 24, April 21, 1987) that the Patent and Trademark Office would now consider non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

2106 Patentable Subject Matter--Mathematical Algorithms or Computer Programs [R-6]

The U.S. Supreme Court decisions in Diamond v. Diehr, 450 U.S. 175, 209 USPQ 1 (1981) and Diamond v. Bradley, 450 U.S. 381, 209 USPQ 97 (1981) significantly affect an examiner's analysis under 35 U.S.C. 101 of patent applications involving mathematical equations, mathematical algorithms and computer programs.

In 35 U.S.C. 101, Congress has set forth the categories of inventions or discoveries which may be patentable as consisting of any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. Inventions involving mathematical equations, mathematical algorithms or computer programs, if statutory at all, would fall into the categories of statutory subject matter as processes, machines or manufactures. In construing 35 U.S.C. 101, the Supreme Court in Diamond v. Diehr, 450 U.S. 175, 209 USPQ 1, 6 (1981) and Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980), has applied a broad interpretation to statutory subject matter so as to include anything under the sun that is made by man.

The Supreme Court also reiterated that certain categories of inventive activity should not be considered statutory subject matter. As set forth in Diamond v. Diehr, 209 USPQ 1, 7 (1981), Excluded from such patent protection are laws of nature, physical phenomena, and abstract ideas. Citing Parker v. Flook, 437 U.S. 584, 198 USPQ 193 (1978); Gottschalk v. Benson, 409 U.S. 63, 175 USPQ 673 (1972). A scientific truth, or the mathematical expression of it, is not a patentable invention, Mackay Radio Corp. & Telegraph Co. v. Radio Corp. of America, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939). In Gottschalk v. Benson,, supra, the Court concluded that an algorithm, or mathematical formula, is like a law of nature, which cannot be the subject of a patent. Similarly, the Court in Parker v. Flook, held that an improved method for computing 'an alarm limit', where the application did not purport to explain now the variables used in the formula were to be selected, nor did the application contain any disclosure relating to the chemical processes at work or the means of setting off an alarm or adjusting the alarm limit, is unpatentable subject matter under 35 U.S.C. 101.(See Diamond v. Diehr, 209 USPQ 1, 10 (1981)).

If the claims of an application are directed solely to one of the above judicially excluded areas of inventive activity, it is clear that a patent shall not issue. However, a claim is not unpatentable under 35 U.S.C. 101 merely because it includes a step(s) or element(s) directed to a law of nature, mathematical algorithm, formula or computer program so long as the claim as a whole is drawn to subject matter otherwise statutory. In this regard, the following significant points of law may be gleaned from the Diamond v. Diehr, 209 USPQ 1 (1981) decision:

1. The claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.. . .The 'novelty' of any element or steps in a process, or even of the process itself, is of *no relevance* in determining whether the subject matter of a claim falls within the 35 U.S.C. 101 categories of possible patentable subject matter (emphasis added).

2. When a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of [35 U.S.C.] 101.

3. When a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract. (If the claim does seek protection for such a mathematical formula, it would be non-statutory under 35 U.S.C. 101).

4. A mathematical formula as such is not accorded the protection of our patent laws . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment. . . . Similarly, insignificant post solution activity will not transform an unpatentable principle into a patentable process.

5. When a claim as in Parker v. Flook, 198 USPQ 193 (1978), is drawn to a method for computing an 'alarm limit' (which) is simply a number, the claim is non-statutory under 35 U.S.C. 101 because Flook sought to protect a formula for computing this number.

6. It is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection. Citing Funk Bros. Seed Co. v. Kalo Co., 333 U.S. 127, 76 USPQ 280 (1948); Eibel Process Co. v. Minnesota and Ontario Paper Co., 261 U.S. 45 (1923); Cochrane v. Deener, 94 U.S. 780 (1876); O'Reilly v. Morse, 15 How. 62 (1853); and Leroy v. Tatham, 14 How. 156 (1852).

35 U.S.C. 101 CLAIM ANALYSIS

In determining eligibility for patent protection under 35 U.S.C. 101, the Supreme Court in Diamond v. Diehr, 209 USPQ 1 (1981), requires that the claims must be considered as a whole. Consistent with this requirement, the Court concluded that a claim drawn to subject matter otherwise statutory does not become non-statutory simply because it uses a mathematical formula, a computer program, or digital computer. Thus, the fact that a claim specifies that a computer performs certain calculation steps is irrelevant for the purpose of determining whether statutory subject matter has been recited. The fact that an application discloses that a mathematical formula is implemented solely by computer programming is likewise immaterial for this purpose.

The Court's requirement that the claims must be considered as a whole in effect leaves viable the CCPA's two-step procedure set forth in In re Freeman, 197 USPQ 464 (CCPA, 1978), as an appropriate test for determining if a claim involving

mathematics and/or computer programming is in compliance with 35 U.S.C. 101. See also In re Walter, 205 USPQ 397 at 407 (CCPA, 1980), for clarification of the second Freeman step. In accordance with the first step of such analysis, each method or apparatus claim must be analyzed to determine whether a mathematical algorithm is either directly or indirectly recited. If the claim at issue fails to directly recite a mathematical algorithm, reference must be made to the specification in order to determine whether claim language indirectly recites mathematical calculations, formulas, or equations.

If a given claim directly or indirectly recites a mathematical algorithm, the second step of the analysis must be applied. Under this step, a determination must be made as to whether the claim as a whole, including all its steps or apparatus elements, merely recites a mathematical algorithm, or method of calculation. If so the claim does not recite statutory subject matter under 35 U.S.C. 101.

The Supreme Court in Diamond v. Diehr, 209 USPQ 1 (1981), provides some guidance in determining whether the claim as a whole merely recites a mathematical algorithm or method of calculation. The Court suggests that if a claim containing a mathematical formula implements or applies that formula in a structure or process which, when *considered as a whole*, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of [35 U.S.C.] 101. (emphasis added)

Focusing on the application or implementation of a mathematical algorithm, the Supreme Court in Diehr, 209 USPQ 1 at 89 (1981), citing Mackay Radio Corp. & Telegraph Co. v. Radio Corp. of America, 306 US 86, 94, 40 USPQ 199, 202 (1939), explained that while a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of a scientific truth may be. In this regard, the CCPA noted in In re Walter, 205 USPQ 397 at 407, (CCPA, 1980), that If it appears that the mathematical algorithm is implemented in a specific manner to define structural relationship between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claims), the claim being otherwise statutory, the claim passes muster under [35 U.S.C.] 101.

The Walter analysis quoted above does not limit patentable subject matter to claims in which structural relationships or process steps are defined, limited, or refined by the

application of the algorithm. In the post Diehr CCPA decision In re Abele, 214 USPQ 682 at 687 (CCPA, 1982), the court urged that Walter should be read broadly to require no more than that the algorithm be applied in any manner to physical elements or process steps provided that its application is circumscribed by more than a field of use limitation or non-essential post-solution activity. Thus, if the claim would be otherwise statutory, id., albeit inoperative or less useful without the algorithm, the claim likewise presents statutory subject matter when the algorithm is included. Also see In re Pardo, 214 USPQ 673 at 676 (CCPA, 1982).

In regard to post-solution activity, the Supreme Court in Diehr indicated that insignificant post-solution activity will not transform an unpatentable principle into a patentable process. The claims in Parker v. Flook, which were held to be non-statutory, recited a post-solution activity of updating a number (i.e., an alarm limit), a step relating more to a method of calculation than to the physical process alluded to in the claim preamble. In Diehr, the Supreme Court characterized the post calculation activity of the type claimed in Parker v. Flook as being token post-solution activity. In contrast, the post-solution activity in the Diehr claims consisted of automatically opening a rubber molding press, a step clearly tied in with the physical process of rubber molding. As stated by the CCPA in In re Walter, 205 USPQ 397 at 407, (CCPA, 1980), if the end-product of a claimed invention is a pure number, as in Benson and Flook, the invention is non-statutory regardless of any post- solution activity which makes it available for use by a person or machine for other purposes.

It must also be recognized that even though a claim contains an application limiting preamble, even though it does not cover every conceivable application of a formula, or even though it does not totally preempt the formula, such a claim would be non-statutory, if, when considered as a whole, it merely recites a mathematical algorithm or method of calculation. As stated by the Supreme Court in Diehr, 209 USPQ 1 at 10, (1981), A mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of that formula to a particular technological use. Similarly, the CCPA pointed out in Walter, 205 USPQ 397 at 409 (1980) that Although the claim preamble relate the claimed invention to the art of seismic prospecting, the claims themselves are not drawn to methods of or apparatus for seismic prospecting; they are drawn to improved mathematical methods for interpreting the results of seismic prospecting. The specific end use recited in the preambles does not save the claims from

the holding in Flook, since they are drawn to methods of calculation, albeit improved. Examination of each claim demonstrates that each has no substance apart from the calculations involved.

Also, in Walter, a Jepson preamble was not regarded as limiting the subject matter as a whole, so as to avoid the 35 U.S.C. 101 rejection. Similarly, preliminary data gathering steps may not affect the subject matter as a whole assessment. In re Richman, 195 USPQ 340, (CCPA 1977). Moreover, even the concluding step of building a bridge or dam may not suffice. In re Sarker, 200 USPQ 132 (CCPA, 1978). In other words, for purposes here, the subject matter as a whole must be viewed in context on a case by case basis.

In analyzing computer program related claims, it is essential to recognize that computer implemented processes are encompassed within 35 U.S.C. 101 under the same principles as other machine implemented processes, subject to judicially determined exceptions, inter alia, mathematical formulas, methods of calculation, and mere ideas. In re Johnson et al, 200 USPQ 199 at 210, 211 (CCPA, 1978). Claims seeking coverage for a computer program implemented process have been held to be statutory by the CCPA in In re Pardo, 214 USPQ 673 (CCPA, 1982), In re Toma, 197 USPQ 852 (CCPA 1978), and In re Chatfield, 191 USPQ 730 (CCPA, 1976). In accordance with the two-step procedure outlined above, claims seeking coverage for a computer program would be non-statutory under 35 U.S.C. 101, only if, when considered as a whole, they merely recite a mathematical algorithm, or a method of calculation which is not applied in any manner to physical elements or process steps. Such an approach is the same as that contemplated for apparatus claims by the CCPA in In re Pardo, 214 USPQ 673 at 677 (CCPA, 1982). See also In re Bradley and Franklin, 202 USPQ 480 (CCPA, 1979).

Certain computer program related claims may be non-statutory under 35 U.S.C. 101 as falling within judicially determined exceptions outside the mathematics area. For example, consider the following claims:

(1) A computer program comprising the steps of:

    a) associating treatment rendered to a patient with a fee, and

        b) billing said patient in accordance with the fee.
Here the computer program is claimed, not in terms of a specific instruction set, but alternatively as a series of steps broadly

defining what the program is designed to accomplish. Such a claim should be viewed as non-statutory under 35 U.S.C. 101 as reciting a method of doing business.

   (2) A computer program for comparing array A(N) with array B(M) to generate array C comprising the steps of:

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Do 70 N = 1,10
Do 80 M = 1,20 If A(N) = B(N) then C(M) = B(M)
80 Continue 70 Continue
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This bare set of instructions fails to recite subject matter that falls within any statutory category. In this regard, a bare set of computer instructions does not set forth a sequence of steps which could be viewed as a statutory process. Such a computer language listing of instructions, when not associated with a computing machine to accomplish a specific purpose, would not constitute a machine implemented process, but would constitute non-statutory subject matter as the mere idea or abstract intellectual concept of a programmer, or as a collection of printed matter.

Further guidance on handling 35 U.S.C. 101 issues may also be gleaned from the CCPA's detailed claim analysis in the following decisions: In re Chatfield, 191 USPQ 730 (CCPA, 1976); In re Johnson, Parrack and Lundsford, 200 USPQ 199 (CCPA, 1979); In re Sarker, 200 USPQ 132 (CCPA, 1978); In re Gelovatch and Arell, 201 USPQ 136 (CCPA, 1979); In re Bradley and Franklin, 202 USPQ 480 (CCPA, 1979); In re Walter, 205 USPQ 397 (CCPA, 1980). In re Taner, 214 USPQ 678 (CCPA, 1982); In re Pardo, 214 USPQ 673 (CCPA, 1982); In re Abele, 214 USPQ 682 (CCPA, 1982); and In re Meyer, 215 USPQ 193 (CCPA, 1982).

In addition to handling 35 U.S.C. 101 issues in accordance with the above analytical approach, it should be emphasized that examiners must also carefully examine mathematical algorithm or computer programming related applications to insure that they comply with the disclosure requirements of 35 U.S.C.112 as well as the novelty and unobviousness requirements of 35 U.S.C. 102 and 35 U.S.C. 103.

2106.01 Computer Programming and 35 U.S.C. 112, First Paragraph [R-6]

The requirements for sufficient disclosure of inventions involving computer programming is the same as for all inventions sought to be patented. Namely, there must be an adequate written description, the original disclosure should be sufficiently

enabling to allow one to make and use the invention as claimed, and there must be presentation of a best mode for carrying out the invention.

The following guidelines, while applicable to a wide range of arts, are intended to provide a guide for analyzing 35 U.S.C. 112, first paragraph, issues in applications involving computer programs, software, firmware, or block diagram cases wherein one or more of the block diagram elements are at least partially comprised of a computer software component. It should be recognized that sufficiency of disclosure issues in computer cases necessarily will require an inquiry into both the sufficiency of the disclosed hardware as well as the disclosed software due to the interrelationship and interdependence of computer hardware and software.

Written Description

The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied upon, the specific subject matter later claimed by him or her; how the specification accomplishes this is not material. In re Herschler, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in In re Kaslow, 217 USPQ 1089 (CAFC 1983).

Best Mode

While the purpose of the best mode requirement is to restrain inventors from applying for patents while at the same time concealing from the public the preferred embodiments of their inventions which they have in fact conceived, In re Gay, 135 USPQ 311, 315 (CCPA 1962); There is no objective standard by which to judge the adequacy of a best mode disclosure. Instead, only evidence of concealment (accidental or intentional) is to be considered. That evidence, in order to result in affirmance of a best mode rejection must tend to show that the quality of an applicant's best mode disclosure is so poor as to effectively result in concealment. In re Sherwood, 204 USPQ 537, 544 (CCPA 1980). Also, see White Consolidated Industries vs Vega Servo-Control, 214 USPQ 796, 824 (S.D. Michigan, S. Div. 1982); affirmed on other grounds; 218 USPQ 961 (CCPA 1983).

Enablement

When basing a rejection on the failure of the applicant's disclosure to meet the enablement provisions of the first paragraph of 35 U.S.C. 112, the examiner must establish on the record that he has a reasonable basis for questioning the

adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. See In re Brown, 177 USPQ 691 (CCPA 1973), In re Ghiron, 169 USPQ 723, (CCPA 1971). Once the examiner has advanced a reasonable basis for questioning the adequacy of the disclosure, it becomes incumbent on the applicant to rebut that challenge and factually demonstrate that his or her application disclosure is in fact sufficient. See In re Doyle, 179 USPQ at 232 (CCPA 1973), In re Scarbrough, 182 USPQ 298, 302 (CCPA 1974), In re Ghiron, Supra.

2106.02 Disclosure in Computer Programming Cases [R-6]

To establish a reasonable basis for questioning the adequacy of a disclosure, the examiner must present a factual analysis of a disclosure to show that a person skilled in the art would not be able to make and use the claimed invention without resorting to undue experimentation.

In computer cases, it is not unusual for the claimed invention to involve two areas of prior art or more than one technology, (White Consolidated, Supra, 214 USPQ at 821); e.g., an appropriately programmed computer and an area of application of said computer. In regard to the skilled in the art standard, in cases involving both the art of computer programming, and another technology, the examiner must recognize that the knowledge of persons skilled in both technologies is the appropriate criteria for determining sufficiency. See In re Naquin, 158 USPQ 317, (CCPA1968); In re Brown, 177 USPQ 691 (CCPA 1973); and White Consolidated, supra at B22.

In a typical computer case, system components are often represented in a block diagram format, i.e., a group of hollow rectangles representing the elements of the system, functionally labelled and interconnected by lines. Such block diagram computer cases may be categorized into 1) systems which include but are more comprehensive than a computer and 2) systems wherein the block elements are totally within the confines of a computer.

BLOCK ELEMENTS MORE COMPREHENSIVE THAN A COMPUTER

The first category of such block diagram cases involves systems which include a computer as well as other system hardware and/or software components. In order to meet his burden of establishing a reasonable basis for questioning the adequacy of such disclosure, the examiner should initiate a factual analysis of

the system by focusing on each of the individual block element components. More specifically, such an inquiry should focus on the diverse functions attributed to each block element as well as the teachings in the specification as to how such a component could be implemented. If based on such an analysis, the examiner can reasonably contend that more than routine experimentation would be required by one of ordinary skill in the art to implement such a component or components, that component or components should specifically be challenged by the examiner as part of a 35 U.S.C. 112, first paragraph rejection. Additionally, the examiner should determine whether certain of the hardware or software components depicted as block elements are themselves complex assemblages which have widely differing characteristics and which must be precisely coordinated with other complex assemblages. Under such circumstances, a reasonable basis may exist for challenging such a functional block diagram form of disclosure. See In re Ghiron, supra, In re Brown, supra.Moreover, even if the applicant has cited prior art patents or publications to demonstrate that particular block diagram hardware or software components are old, it should not always be considered as self evident how such components are to be interconnected to function in a disclosed complex manner. See In re Scarbrough, supra, at 301 and In re Forman, 175 USPQ 12, 16 (CCPA 1972). Furthermore, in complex systems including a digital computer, a microprocessor, or a complex control unit as one of many block diagram elements, timing between various system elements may be of the essence and without a timing chart relating the timed sequences for each element, an unreasonable amount of work may be required to come up with the detailed relationships an applicant alleges that he has solved. See In re Scarbrough, supra at 302.

For example, in a block diagram disclosure of a complex claimed system which includes a microprocessor and other system components controlled by the microprocessor, a mere reference to a prior art, commercially available microprocessor, without any description of the precise operations to be performed by the microprocessor, fails to disclose how such a microprocessor would be properly programmed to either perform any required calculations or to coordinate the other system components in the proper timed sequence to perform the functions disclosed and claimed. If, in such a system, a particular program is disclosed, such a program should be carefully reviewed to insure that its scope is commensurate with the scope of the functions attributed to such a program in the claims. See In re Brown, supra at 695. If the disclosure fails to disclose any program and if more than routine experimentation would be required of one skilled in the art to generate such a program, the examiner

clearly would have a reasonable basis for challenging the
sufficiency of such a disclosure. The amount of experimentation
that is considered routine will vary depending on the facts and
circumstances of individual cases. No exact numerical standard
has been fixed by the courts, but the amount of required
experimentation must, however, be reasonable (White
Consolidated, Supra, at 963. One court apparently found that the
amount of experimentation involved was reasonable where a
skilled programmer was able to write a general computer program,
implementing an embodiment form, within four hours.
(Hirschfield, Supra, at 279 et seq.). On the other hand, another
court found that, where the required period of experimentation
for skilled programmers to develop a particular program would
run to 1 1/2 to 2 man) years, this would be a clearly
unreasonable requirement (White Consolidated, supra at 963).

BLOCK ELEMENTS WITHIN A COMPUTER

The second category of block diagram cases occurs most
frequently in pure data processing applications where the
combination of block elements is totally within the confines of
a computer, there being no interfacing with external apparatus
other than normal input/output devices. In some instances, it
has been found that particular kinds of block diagram
disclosures were sufficient to meet the enabling requirement of
35 U.S.C. 112, first paragraph. See In re Knowlton, 178 USPQ 486
(CCPA 1973), In re Comstock and Gilmer, 178 USPQ 616 (CCPA
1973). Most significantly, however, in both the Comstock and
Knowlton cases, the decisions turned on the appellants'
disclosure of 1) a reference to and reliance on an identified
prior art computer system and 2) an operative computer program
for the referenced prior art computer system. Moreover, in
Knowlton the disclosure was presented in such a detailed fashion
that the individual program's steps were specifically
interrelated with the operative structural elements in the
referenced prior art computer system. The Court in Knowlton
indicating that the disclosure did not merely consist of a
sketchy explanation of flow diagrams or a bare group of program
listings together with a reference to a proprietary computer in
which they might be run. The disclosure was characterized as
going into considerable detail into explaining the
interrelationships between the disclosed hardware and software
elements. Under such circumstances, the Court considered the
disclosure to be concise as well as full, clear and exact to a
sufficient degree to satisfy the literal language of 35 U.S.C.
112, first paragraph. It must be emphasized that because of the
significance of the program listing and the reference to and
reliance on an identified prior art computer system, absent

either of these items, a block element disclosure within the confines of a computer should be scrutinized in precisely the same manner as the first category of block diagram cases discussed above.

Regardless of whether a disclosure involves block elements more comprehensive than a computer or block elements totally within the confines of a computer, the examiner, when analyzing method claims, must recognize that the specification must be adequate to teach how to practice the claimed method. If such practice requires particular apparatus, it is axiomatic that the application must therefore provide a sufficient disclosure of that apparatus if such is not already available. See In re Ghiron, supra at 727 and In re Gunn, 190 USPQ 402, 406 (CCPA 1976). When the examiner questions the adequacy of computer system or computer programming disclosures, the examiner's reasons for finding the specification to be non-enabling should be supported by the record as a whole. In this regard, it is also essential for the examiner to reasonably challenge evidence submitted by the applicant. For example, in In re Naquin, supra, an affiant's statement unchallenged by the examiner, that the average computer programmer was familiar with the subroutine necessary for performing the claimed process, was held to be a statement of fact which rendered the examiner's rejection baseless. In other words, unless the examiner presents a reasonable basis for challenging the disclosure in view of the record as a whole, a 35 U.S.C. 112, first paragraph rejection in a computer system or computer programming case will not be sustained on appeal. See In re Naquin, supra, In re Morehouse and Bolton, 192 USPQ 29, 32 (CCPA 1976).

While no specific universally applicable rule exists for recognizing an insufficiently disclosed application involving computer programs, an examining guideline to generally follow is to challenge the sufficiency of such disclosures which fail to include either the computer program itself or a reasonably detailed flowchart which delineates the sequence of operations the program must perform. In programming applications whose software disclosure only includes a flowchart, as the complexity of functions and the generality of the individual components of the flowchart increase, the basis for challenging the sufficiency of such a flowchart becomes more reasonable because the likelihood of more than routine experimentation being required to generate a working program from such a flowchart also increases.
As stated earlier, once an examiner has advanced a reasonable basis or presented evidence to question the adequacy of a computer system or computer programming disclosure, the

applicant must show that his or her specification would enable one of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. In most cases, efforts to meet this burden involve submitting affidavits, referencing prior art patents or technical publications, arguments of counsel or combinations of these approaches

AFFIDAVIT PRACTICE (37 CFR 1.132)

In computer cases, affidavits must be critically analyzed. Affidavit practice usually initially involves analyzing the skill level and/or qualifications of the affiant, which should be of the routineer in the art. When an affiant's skill level is higher than that required by the routineer for a particular application, an examiner may challenge the affidavit since it would not be made by a routineer in the art, and therefore would not be probative as to the amount of experimentation required by a routineer in the art to implement the invention. An affiant having a skill level or qualifications above that of the routineer in the art would require less experimentation to implement the claimed invention than that for the routineer. Similarly, an affiant having a skill level or qualifications below that of the routineer in the art would require more experimentation to implement the claimed invention than that for the routineer in the art. In either situation, the standard of the routineer in the art would not have been met.

In computer systems or programming cases, the problems with a given affidavit, which relate to the sufficiency of disclosure issue, generally involve affiants submitting few facts to support their conclusions or opinions. Some affidavits may go so far as to present conclusions on the ultimate legal question of sufficiency. In re Brandstadter, Kienzle and Sykes, 179 USPQ 286 (CCPA 1973) illustrates the extent of the inquiry into the factual basis underlying an affiant's conclusions or opinions. In Brandstadter, the invention concerned a stored program controller (computer) programmed to control the storing, retrieving and forwarding of messages in a communications system. The disclosure consisted of broadly defined block diagrams of the structure of the invention and no flowcharts or program listings of the programs of the controller. The Court quoted extensively from the Examiner's Office Actions and Examiner's Answer in its opinion where it was apparent that the Examiner consistently argued that the disclosure was merely a broad system diagram in the form of labelled block diagrams along with statements of a myriad of desired results. Various affidavits were presented in which the affiants stated that all

or some of the system circuit elements in the block diagrams were either well known in the art or could be constructed by the skilled design engineer, that the controller was capable of being programmed to perform the stated functions or results desired, and that the routineer in the art could design or construct or was able to program the system. The Court did consider the affiants' statements as being some evidence on the ultimate legal question of enablement but concluded that the statements failed in their purpose since they recited conclusions or opinions with few facts to support or buttress these conclusions. With reference to the lack of a disclosed computer program or even a flow chart of the program to control the message switching system, the record contained no evidence as to the number of programmers needed, the number of man-hours and the level of skill of the programmers to produce the program required to practice the invention.

It should be noted also that it is not opinion evidence directed to the ultimate legal question of enablement, but rather factual evidence directed to the amount of time and effort and level of knowledge required for the practice of the invention from the disclosure alone which can be expected to rebut a prima facie case of nonenablement. See Hirschfield v. Banner, Commissioner of Patents and Trademarks, 200 USPQ 276, 281 (D.D.C. 1978). It has also been held that where an inventor described the problem to be solved to an affiant, thus enabling the affiant to generate a computer program to solve the problem, such an affidavit failed to demonstrate that the application alone would have taught a person of ordinary skill in the art how to make and use the claimed invention. See In re Brown, supra at 695. The Court indicated that it was not factually established that the applicant did not convey to the affiant vital and additional information in their several meetings in addition to that set out in the application. Also of significance for an affidavit to be relevant to the determination of enablement is that it must be probative of the level of skill of the routineer in the art as of the time the applicant filed his application. See In re Gunn, supra at, 406. In this case each of the affiants stated what was known at the time he executed the affidavit, and not what was known at the time the applicant filed his application.

REFERENCING PRIOR ART DOCUMENTS

Earlier it has been discussed that citing in the specification the commercial availability of an identified prior art computer system is very pertinent to the issue of enablement. But in some cases, this approach may not be sufficient to meet the applicant's burden. Merely citing in an affidavit extracts from

technical publications in order to satisfy the enablement requirement is not sufficient if it is not made clear that a person skilled in the art would know which, or what parts, of the cited circuits could be used to construct the claimed device or how they could be interconnected to act in combination to produce the required results. See In re Forman, supra at 16. This analysis would appear to be less critical where the circuits comprising applicant's system are essentially standard components comprising an identified prior art computer system and a standard device attached thereto.

Prior art patents are often relied on by applicants to show the state of the art for purposes of enablement. However, these patents must have an issue date earlier than the effective filing date of the application under consideration. See In re Budnick, 190 USPQ 422, 424 (CCPA 1976). An analogous point was made in In re Gunn, supra where the court indicated that patents issued after the filing date of the applicant's application are not evidence of subject matter known to any person skilled in the art since their subject matter may have been known only to the patentees and the Patent and Trademark Office.

Merely citing prior art patents to demonstrate that the challenged components are old may not be sufficient proof since, even if each of the enumerated devices or labelled blocks in a block diagram disclosure were old per se, this would not make it self-evident how each would be interconnected to function in a disclosed complex combination manner. Therefore, the specification in effect must set forth the integration of the prior art, otherwise it is likely that undue experimentation, or more than routine experimentation would be required to implement the claimed invention. See In re Scarbrough, supra at 301. The Court also noted that any cited patents which are used by the applicant to demonstrate that particular box diagram hardware or software components are old must be analyzed as to whether such patents are germane to the instant invention and as to whether such components provide better detail of disclosure as to such components than an applicant's own disclosure. Also any patent or publication cited to provide evidence that a particular programming technique is well known in the programming art does not demonstrate that one of ordinary skill in the art could make and use correspondingly disclosed programming techniques unless both programming techniques are of approximately the same degree or complexity. See In re Knowlton, supra at 37 (CCPA 1974).
ARGUMENTS OF COUNSEL

Arguments of counsel may be effective in establishing that an examiner has not properly met his or her burden or has otherwise

erred in his or her position. In these situations, an examiner may have failed to set forth any basis for questioning the adequacy of the disclosure or may have not considered the whole specification, including the drawings and the written description. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, supra at, 424;In re Schulze, 145 USPQ 716 (CCPA 1965); and In re Cole, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the Court indicated that factual affidavits could have provided important evidence on the issue of enablement. See In re Knowlton, supra at, 37 and In re Wiseman, 201 USPQ 658 (CCPA 1979).