**Examination Guidelines for 35 U.S.C. § 102(e), as amended by the American Inventors Protection Act of 1999, and further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, and 35 U.S.C. § 102(g)**

This notice sets forth the interpretation by the United States Patent and Trademark Office (USPTO or Office) of 35 U.S.C. §§ 102(e) and 374, as amended by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)), and as further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)). This notice also clarifies the Office's policy on prior art rejections based on 35 U.S.C. § 102(g).

Generally, 35 U.S.C. § 102(e), after enactment of the AIPA and H.R. 2215, is similar to the pre-AIPA § 102(e), with two significant differences, which may be summarized as: (1) in addition to U.S. patents, now certain **publications** of U.S. and international applications may be applied as of their filing dates in a prior art rejection; and (2) **certain international filing dates** are now U.S. filing dates for prior art purposes under § 102(e), and U.S. patents and certain application publications may now be applied as of these international filing dates in a prior art rejection.

Specifically, this notice provides guidance that prior art, as defined by § 102(e) of the patent code in effect on November 29, 2000, includes U.S. patents, publications of U.S. patent applications and World Intellectual Property Organization's (WIPO) publications of international applications, provided such references do not directly or indirectly result from an international application filed before November 29, 2000. If a U.S. patent resulted from an international application filed before November 29, 2000, the U.S. patent will have a prior art date per § 102(e) in effect prior to November 29, 2000, which is the earlier of the date of compliance with § 371(c)(1), (2) and (4) of the patent code (e.g. National Stage entry) or the filing date of the later-filed U.S. application that claimed the benefit of the international application. A U.S. or WIPO publication of an international application filed prior to November 29, 2000 will have no prior art effect under § 102(e). Such publications do, however, have prior art effect under § 102(a) or (b) as of their publication dates.

Furthermore, all pending U.S. patent applications being examined, and all U.S. patents being reexamined, or otherwise being contested, whenever filed, are subject to the amended version of § 102(e).

This notice also provides examples of the determination of § 102(e) dates for references based on the most common factual scenarios. The examples that best highlight the recent change to §§ 102(e) and 374 are the examples that involve a WIPO publication of an international application under PCT Article 21(2), a U.S. publication of an international application, or a U.S. patent derived from an international application.

The policy and practice set forth in the Official Gazette Notice entitled "Examination Guidelines for 35 U.S.C. § 102(e)(2), as amended by the American Inventors Protection

Act of 1999," 1243 O.G. 1037 (Feb. 27, 2001) and guidelines provided in the Manual of Patent Examining Procedure (MPEP) concerning the changes made by the AIPA to 35 U.S.C. § 102(e) (e.g., MPEP 706.02(a), Part II; 901.03; 1895.01, Part E; 1896; and 2136 et seq., Eighth Edition (August 2001)) are superceded by this notice and should no longer be followed.

SIGNIFICANT PROVISIONS:

**A. Effective Date Provisions of the Amendments.**
The technical correction legislation in H.R. 2215 provides for the application of revised 35 U.S.C. § 102(e) in the examination of all applications, whenever filed, and the reexamination of, or other proceedings to contest, all patents. The filing date of the application is no longer relevant in determining what version of § 102(e) to apply in determining the patentability of that application, or the patent resulting from that application. The revised statutory provisions supercede all previous versions of §§ 102(e) and 374, with only one exception, which is when the potential reference is based on an international application filed prior to November 29, 2000 (discussed further in section D below). Furthermore, the provisions amending §§ 102(e) and 374 in H.R. 2215 are completely retroactive to the effective date of the relevant provisions in the AIPA (November 29, 2000).

**B. U.S. and WIPO application publications may have a § 102(e)(1) prior art date.**
Paragraph (e) of 35 U.S.C. § 102 was amended by the AIPA to create two separate clauses, namely, § 102(e)(1) for **publications** of patent applications and § 102(e)(2) for patents. Section 102(e)(1), in combination with amended § 374, created a new category of prior art by providing prior art effect for certain **publications** of patent applications, including international applications, as of their effective United States filing dates (which will include certain international filing dates). Under H.R. 2215's revised § 102(e), an international filing date, which is on or after November 29, 2000, is a United States filing date if the international application designated the United States and was published by the World Intellectual Property Organization (WIPO) under the Patent Cooperation Treaty (PCT) Article 21(2) in the English language. Publication under PCT Article 21(2) may result from a request for early publication by an international applicant or after the expiration of 18-months after the earliest claimed filing date in an international application. An applicant that has designated only the U.S. would continue to be required to request publication from WIPO as the reservation under PCT Article 64(4) continues to be in effect for such applicants.

**C. A patent from an international application may have a § 102(e)(2) prior art date of its international filing date.**
Paragraph (e) of 35 U.S.C. § 102 was also amended by the AIPA to eliminate the reference to fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements. As a result, United States **patents** issued directly from international applications filed on or after November 29, 2000 will no longer be available as prior art under § 102(e) as of the date the requirements of § 371 (c)(1), (2) and (4) have been satisfied. Under § 102(e)(2), as amended by the AIPA and H.R. 2215, an international filing date, which is on or after

November 29, 2000, is a United States filing date for purposes of determining the earliest effective prior art date of a patent if the international application designated the United States and was published in the English language under PCT Article 21(2) by WIPO.

**D. International filing dates prior to November 29, 2000 cannot be used under § 102(e) for prior art purposes.**

No international filing dates prior to November 29, 2000 may be relied upon as a prior art date under § 102(e) in accordance with the last sentence of the effective date provisions (reproduced below in section I). **Patents** issued directly, or indirectly, from international applications filed before November 29, 2000 may only be used as prior art based on the provisions of § 102(e) in effect before November 29, 2000. Thus, the date of such a prior art patent is the earliest of the date of compliance with 35 U.S.C. § 371(c)(1), (2) and (4), or the filing date of the later-filed U.S. continuing application that claimed the benefit of the international application. **Publications** of international applications filed before November 29, 2000 (which would include WIPO publications and U.S. publications of the National Stage (§ 371)) do not have a § 102(e) date at all. Specifically, under § 374, the international application must be filed on or after November 29, 2000 for its WIPO publication to be "deemed a publication under section 122(b)" and thus available as a possible prior art reference under § 102(e) as amended by the AIPA.

**E. Additional requirements for international applications filed on or after November 29, 2000.**

If an international application was filed on or after November 29, 2000, the international application must have **designated the U.S.** and been **published in English** under PCT Article 21(2) by WIPO in order for its international filing date to be a U.S. filing date for purposes of § 102(e) and be relied upon as a prior art date.

**F. When an international application cannot serve as a bridge to an earlier-filed application.**

International applications, which: (1) were filed prior to November 29, 2000, (2) did not designate the U.S., or (3) were not published in English under PCT Article 21(2) by WIPO, may not be used to reach back (bridge) to an earlier filing date through a priority or benefit claim for prior art purposes under 35 U.S.C. § 102(e).

DISCUSSION: Sections I–V below set forth the USPTO's examination procedures for the amendments to 35 U.S.C. § 102(e) made by the AIPA and H.R. 2215.

**I) Statutory Language of 35 U.S.C. §§ 102(e) and 374:**

*Pre-AIPA § 102(e): Now, only applies to Patents derived from International Applications filed before November 29, 2000:*

> "A person shall be entitled to a patent unless —
> (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 applicant for patent, or".

*Revised § 102(e): For examining all Applications, whenever filed, and for reexamining of all Patents, and for determining the prior art dates[1] of Patents and certain Application Publications:*

> A person shall be entitled to a patent unless
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language; or

*Pre-AIPA § 374: For WIPO Publications of International Applications filed prior to November 29, 2000:*

> The publication under the treaty of an international application shall confer no rights and shall have no effect under this title other than that of a printed publication.

*Revised § 374: For WIPO Publications of International Applications filed on or after November 29, 2000:*

> The publication under the treaty defined in section 351(a) of this title, of an international application designating the United States shall be deemed a publication under section 122(b), except as provided in sections 102(e) and 154(d) of this title.

*Effective Date Provisions for the amendments to §§ 102(e) and 374[2], as amended by H.R. 2215:*

> Except as otherwise provided in this section, sections 4502 through 4504 and 4506 through 4507, and the amendments made by such sections, shall be effective as of November 29, 2000, and shall apply only to applications (including international applications designating the United States) filed on or after that date. The amendments made by section 4504 shall additionally apply to any pending application filed before November 29, 2000, if such pending application is published pursuant to a request of the

applicant under such procedures as may be established by the Director. Except as otherwise provided in this section, the amendments made by section 4505 shall be effective as of November 29, 2000 and shall apply to all patents and all applications for patents pending on or filed after November 29, 2000. Patents resulting from an international application filed before November 29, 2000 and applications published pursuant to section 122(b) or Article 21(2) of the treaty defined in section 351(a) resulting from an international application filed before November 29, 2000 shall not be effective as prior art as of the filing date of the international application; however, such patents shall be effective as prior art in accordance with section 102(e) in effect on November 28, 2000.

## II) Impact of Statutory Changes and Effective Date of the Changes

As shown above, 35 U.S.C. § 102(e) has been amended to have two separate clauses, namely, **(e)(1)** for **publications** of patent applications, and **(e)(2)** for **patents**.

With respect to revised 35 U.S.C. § 102(e)(1) and 35 U.S.C. § 374, a new category of prior art is created for **publications** of patent applications. This new category includes the following two types of published patent applications:

(1) U.S. publications of patent applications filed in the United States by another which are published under § 122(b) of title 35, United States Code; and

(2) U.S. and WIPO publications of international applications, filed on or after November 29, 2000, by another that designated the United States and were published in the English language under PCT Article 21(2) by WIPO.

In summary, under amended §§ 102(e)(1) and 374, **publications** of patent applications, including certain WIPO publications of international applications (under PCT Article 21(2)) which are filed on or after November 29, 2000, are considered to be prior art as of their earliest effective United States filing date. It is important to note that a U.S. application publication of a National Stage of an international application or a WIPO publication of an **international application** under §§ 102(e)(1) and 374, as amended by H.R. 2215, can be prior art as of the international filing date if the international application had an international **filing date on or after November 29, 2000, designated the United States**, and was **published in English** under PCT Article 21(2) by WIPO. Prior to the AIPA amendments to §§ 102(e) and 374, a WIPO publication of an international application could only be prior art under § 102(a) or (b) as of the publication date (and there were no U.S. application publications).

Paragraph (e) of 35 U.S.C. § 102 was also amended to modify what U.S. **patents** are available as prior art under this subsection. Section 102(e)(2) no longer recognizes the date of fulfillment of the 35 U.S.C. § 371(c)(1), (2) and (4) requirements for prior art purposes. Section § 102(e)(2), however, considers an international filing date that is on or after November 29, 2000 as a United States filing date for purposes of determining the earliest effective prior art date of a patent if the international application designated the

United States and was published in the English language under PCT Article 21(2) by WIPO.

The AIPA and H.R. 2215 also establish when the amendments to §§ 102(e) and 374 must be applied. First, the AIPA and H.R. 2215 set forth that the amendments to § 102(e) apply to all applications being examined and all patents under reexamination. See the third sentence of § 4508 of the AIPA, as amended by H.R. 2215 (addressing § 4505 of the AIPA). In other words, the revised version of § 102(e) is completely retroactive, and it applies to all applications, no matter when filed, and all patents, with only one exception, which pertains to applying, as prior art under § 102(e), patents or publications based on international applications filed prior to November 29, 2000. Further, the amendments to § 374, which "deems" certain WIPO publications of international applications under PCT Article 21(2) as U.S. publications of applications filed under 35 U.S.C. § 111(a), are only effective for international applications filed on or after November 29, 2000. Therefore, an international application must be filed on or after November 29, 2000 for its WIPO publication to be "deemed a publication under section 122(b)," and thus available as a possible prior art reference under § 102(e)(1).

**III) Prior Art Rejections based on 35 U.S.C. § 102(g)**

35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence, while more commonly applied to interference matters, also arise in other contexts.

35 U.S.C. § 102(g) may form the basis for an *ex parte* rejection if: (1) the subject matter at issue has been actually reduced to practice by another before the applicant's invention, and (2) there has been no abandonment, suppression or concealment. *See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1205, 18 USPQ2d 1016, 1020 (Fed. Cir. 1991); *New Idea Farm Equipment Corp. v. Sperry Corp.*, 916 F.2d 1561, 1566, 16 USPQ2d 1424, 1428 (Fed. Cir. 1990); *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434, 7 USPQ2d 1129, 1132 (Fed. Cir. 1988); *Kimberly_Clark v. Johnson & Johnson*, 745 F.2d 1437, 1444-46, 223 USPQ 603, 606-08 (Fed. Cir. 1984). To qualify as prior art under 35 U.S.C. § 102(g), however, there must be evidence that the subject matter was actually reduced to practice, in that conception alone is not sufficient. *See Kimberly Clark*, 745 F.2d at 1445, 223 USPQ at 607. While the filing of an application for patent is a constructive reduction to practice, the filing of an application does not in itself provide the evidence necessary to show an actual reduction to practice of any of the subject matter disclosed in the application as is necessary to provide the basis for an *ex parte* rejection under 35 U.S.C. § 102(g). Thus, absent evidence showing an actual reduction to practice (which is generally not available during *ex parte* examination), the disclosure of a United States patent application publication or patent falls under 35 U.S.C. § 102(e) and not under 35 U.S.C. § 102(g). *Cf. In re Zletz*, 893 F.2d 319, 323, 13 USPQ2d 1320, 1323 (Fed. Cir. 1990) (the disclosure in a reference United States patent does not fall under 35 U.S.C. § 102(g) but under 35 U.S.C. § 102(e)).

In addition, subject matter qualifying as prior art only under 35 U.S.C. § 102(g) may also be the basis for an *ex parte* rejection under 35 U.S.C. 103. *See In re Bass*, 474 F.2d 1276, 1283, 177 USPQ 178, 183 (CCPA 1973) (in an unsuccessful attempt to utilize a 37 CFR 1.131 affidavit relating to a combination application, applicants admitted that the subcombination screen of a copending application which issued as a patent was earlier conceived than the combination). 35 U.S.C. § 103(c), however, states that subsection (g) of 35 U.S.C. § 102 will not preclude patentability where subject matter developed by another person, that would otherwise qualify under 35 U.S.C. § 102(g), and the claimed invention of an application under examination were owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made. See MPEP §§ 706.02(l) and 2146 (Eighth Edition (Aug. 2001)).

For additional examples of 35 U.S.C. § 102(g) issues such as conception, reduction to practice and diligence outside the context of interference matters, see *In re Costello*, 717 F.2d 1346, 219 USPQ 389 (Fed. Cir. 1983) (discussing the concepts of conception and constructive reduction to practice in the context of a declaration under 37 CFR 1.131), and *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973) (holding constructive reduction to practice for priority under 35 U.S.C. § 119 requires meeting the requirements of 35 U.S.C. §§ 101 and 112).

## IV) Examination Procedures under 35 U.S.C. §§ 102(e) and 374

(1) Determine the effective filing date(s) of the application being examined.
See the Manual of Patent Examining Procedure (MPEP), sections 706.02, 1893.03(b), 1893.03(c), 1895 and 1895.01, Eighth Edition (Aug. 2001) as revised by this notice.

(2) Determine and perform an appropriate prior art search.
The Examiner should search for the most relevant prior art under 35 U.S.C. §§ 102 and 103, including U.S. and WIPO **publications** of patent applications, and U.S. **patents** accorded prior art dates under § 102(e).

(3) Determine if the potential reference under § 102(e) is "by another."
The inventive entity of the application must be different than that of the reference in order to apply a reference under § 102(e). Note that, where there are joint inventors, only one inventor need be different for the inventive entities to be different and a rejection under § 102(e) may be applicable even if there are some common inventors. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.

(4) Determine the appropriate § 102(e) date for each potential reference by following the guidelines below and examples set forth under Part V:
   (a) The potential reference must be a U.S. patent, a U.S. application publication (35 U.S.C. § 122(b)) or a WIPO publication of an international application under PCT Article 21(2) in order to apply the reference under § 102(e).

(b) Determine if the potential reference resulted from, or claimed the benefit of, an international application. If the reference does, go to step (c) below.

The § 102(e) date of a reference that did not result from, nor claimed the benefit of, an international application is its earliest effective U.S. filing date, taking into consideration any proper priority or benefit claims to prior U.S. applications under §§ 119(e) or 120 if the prior application(s) properly supports the subject matter used to make the rejection. See MPEP 706.02(a), Eighth Edition (Aug. 2001) as revised by this notice.

(c) If the potential reference resulted from, or claimed the benefit of, an international application, the following must be determined:

i. If the international application meets the following three conditions:

1. an international filing date on or after November 29, 2000;
2. designated the United States; and
3. published under PCT Article 21(2) in English,

the international filing date is a U.S. filing date for prior art purposes under § 102(e). If such an international application properly claims benefit to an earlier-filed U.S. or international application, or priority to an earlier-filed U.S. provisional application, apply the reference under § 102(e) as of the earlier filing date, assuming all the conditions of §§ 102(e), 119(e), 120, or 365(c) are met. Note, where the earlier application is an international application, the earlier international application must satisfy the same three conditions (i.e., filed on or after November 29, 2000, designated the U.S. and had been published in English under PCT Article 21(2)).

ii. If the international application was filed on or after November 29, 2000, but did **not** designate the United States or was **not** published in English under PCT Article 21(2), do **not** treat the international filing date as a U.S. filing date. In this situation, do **not** apply the reference as of its international filing date, its date of completion of the § 371(c)(1), (2) and (4) requirements, or any earlier filing date to which such an international application claims benefit or priority. The reference may be applied under § 102(a) or (b) as of its publication date, or § 102(e) as of any later U.S. filing date of an application that properly claimed the benefit of the international application (if applicable).

iii. If the international application has an international filing date prior to November 29, 2000, apply the reference under the provisions of §§ 102 and 374, prior to the AIPA amendments:

1. For U.S. patents, apply the reference under § 102(e) as of the earlier of the date of completion of the requirements of § 371(c)(1), (2) and (4) or the filing date of the later-filed

U.S. application that claimed the benefit of the international application.

2. For U.S. application publications and WIPO publications of international applications under PCT Article 21(2), never apply these references under § 102(e). These references may be applied as of their publication dates under § 102(a) or (b).
3. For U.S. application publications of applications that claim the benefit of an international application filed prior to November 29, 2000, apply the reference under § 102(e) as of the actual filing date of the later-filed U.S. application that claimed the benefit of the international application.

iv. Examiners should be aware that although a publication of, or a U.S. Patent issued from, an international application may not have a § 102(e) date at all, or may have a § 102(e) date that is after the effective filing date of the application being examined (so it is not "prior art"), the corresponding WIPO publication of an international application will likely have an earlier § 102(a) or (b) date.

(d) Foreign applications' filing dates that are claimed (via 35 U.S.C. §§ 119(a)-(d) or 365(a)) in applications, which have been published as U.S. or WIPO application publications or patented in the U.S., may **not** be used as § 102(e) dates for prior art purposes. This would include international filing dates claimed as foreign priority dates under 35 U.S.C. § 365(a).

(5) Determine whether 35 U.S.C. § 103(c) common assignee considerations apply.

If a § 102(e) reference is applied in an obviousness rejection under 35 U.S.C. § 103(a) (including provisional rejections) in an application filed on or after November 29, 1999[3], the examiner should ascertain whether there is evidence that the claimed invention and the reference were owned by the same person, or subject to an obligation of assignment to the same person, at the time the claimed invention was made. A clear statement of entitlement to the prior art exclusion by applicant(s) or a registered practitioner would be sufficient evidence to establish the prior art exclusion. A double patenting rejection, however, based on the § 102(e) reference could be applied, if appropriate, even if the reference is disqualified from being used a rejection under § 103(a). See MPEP 706.02(l), Eighth Edition (Aug. 2001).

(6) Apply the reference(s) under §§ 102 or 103, based on the provision of § 102 that gives the best prior art date for the disclosure. If a reference is prior art under both §§ 102 (a) and (e), but not § 102(b), the reference should be applied under both provisions.

(a) Examiners should provide a copy of the appropriate statutory language under which the rejection is made in the first Office action utilizing such a

rejection. Only revised (October 2002, or more current) Form Paragraphs pertaining to § 102(e) should be used.

(7) Final rejection practice: If a second or subsequent action contains a new ground of rejection necessitated by the change to 35 U.S.C. § 102(e) that was not also necessitated by an amendment to the claims or as a result of certain information disclosure statements, that action cannot be made final. See MPEP 706.07(a), Eighth Edition (Aug. 2001).

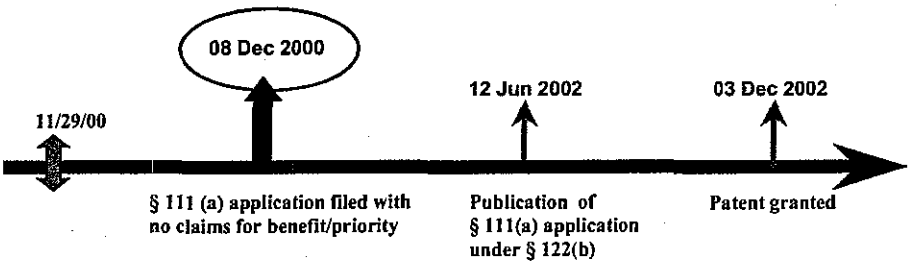
## V) Examples

In order to illustrate the prior art dates of U.S. and WIPO **publications** of patent applications and United States **patents** under § 102(e), nine examples are presented below. The examples only cover the most common factual situations that might be encountered when determining the § 102(e) date of a reference. Examples 1 and 2 involve only U.S. application publications and U.S. patents. Example 3 involves a priority claim to a foreign patent application. Examples 4-9 involve international applications. The **time lines** in the examples below show the history of the prior art **references** that could be applied against the claims of the application under examination, or the patent under reexamination.

The dates in the examples below are arbitrarily used and are presented for illustrative purposes only. Therefore, correlation of patent grant dates with Tuesdays or application publication dates with Thursdays may not be portrayed in the examples.

**Example 1:** Reference Publication and Patent of § 111(a) Application with no Priority/Benefit Claims

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a) with no claim for the benefit of, or priority to, a prior application, the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing date. Thus, a publication and patent of a § 111(a) application, which does not claim any benefit under either 35 U.S.C. §§ 119(e), 120 or 365(c), would be accorded the application's actual filing date as its prior art date under § 102(e).




The § 102(e)(1) date for Publication is: 08 Dec 2000

The § 102(e)(2) date for the Patent is: 08 Dec 2000

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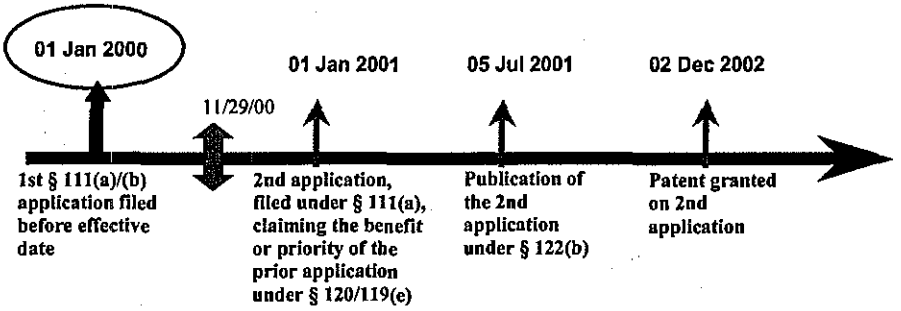
**Example 2:** Reference Publication and Patent of § 111(a) Application with Priority/Benefit Claim to a Prior U.S. Provisional or Nonprovisional Application

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. Thus, a publication and patent of a § 111(a) application, which claims priority under 35 U.S.C. § 119(e) to a prior U.S. provisional application or claims the benefit under 35 U.S.C. § 120 of a prior nonprovisional application, would be accorded the earlier filing date as its prior art date under § 102(e), assuming the earlier-filed application has proper support for the subject matter as required by §§ 119(e) or 120.




The § 102(e)(1) date for Publication is: 01 Jan 2000
The § 102(e)(2) date for the Patent is: 01 Jan 2000

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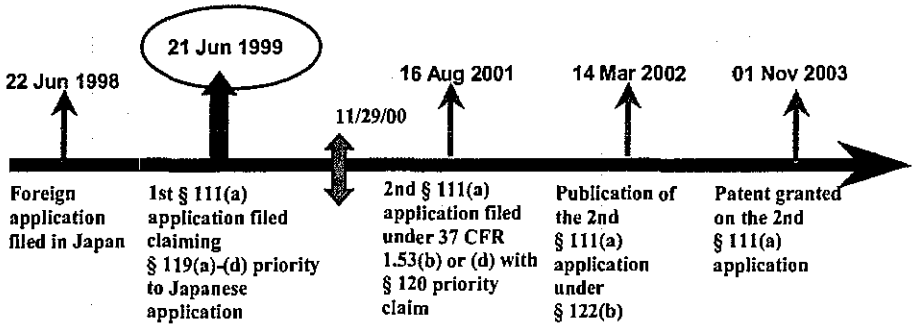
**Example 3:** Reference Publication and Patent of § 111(a) Application with § 119(a)-(d) Benefit Claim to a Prior Foreign Application

For reference publications and patents of patent applications filed under 35 U.S.C. § 111(a), the prior art dates under § 102(e) accorded to these references are the earliest effective United States filing dates. No benefit of the filing date of the foreign application is given under § 102(e) for prior art purposes (*In re Hilmer*, 149 USPQ 480 (CCPA 1966)). Thus, a publication and patent of a § 111(a) application, which claims benefit under 35 U.S.C. § 119(a)-(d) to a prior foreign-filed application, would be accorded its United States filing date as its prior art date under § 102(e).



The § 102(e)(1) date for Publication is: 21 Jun 1999
The § 102(e)(2) date for the Patent is: 21 Jun 1999

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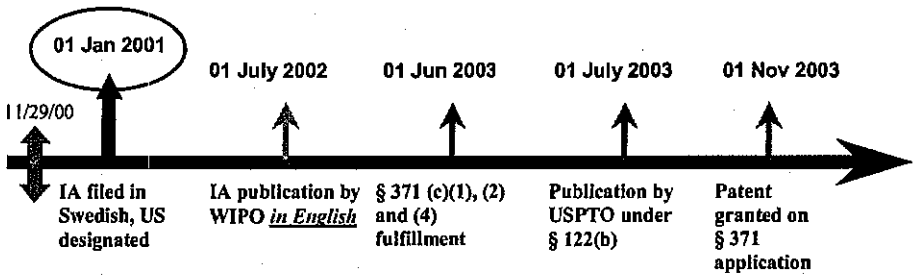
**Example 4:** References based on the **National Stage (§ 371)** of an **International Application filed on or after November 29, 2000** and which was published in **English** under PCT Article 21(2).

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that were filed on or after November 29, 2000, designated the U.S., and were published in English under PCT Article 21(2) by WIPO have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English.



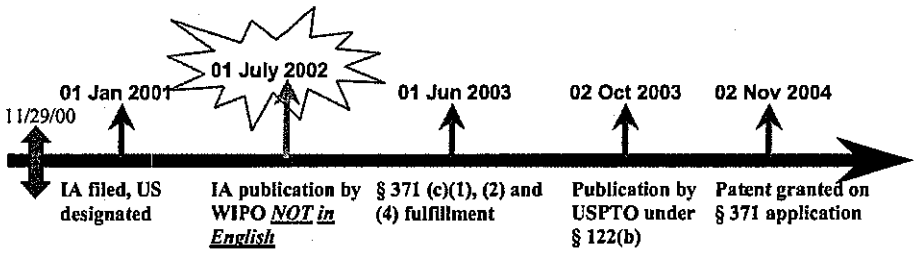

The § 102(e)(1) date for the IA publication by WIPO is: 01 Jan 2001
The § 102(e)(1) date for Publication by USPTO is: 01 Jan 2001
The § 102(e)(2) date for the Patent is: 01 Jan 2001

Additional Priority/Benefit Claims:

- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the international filing date, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120.
- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.

**Example 5:** References based on the **National Stage (§ 371)** of an **International Application filed on or after November 29, 2000** and which was **not** published in **English** under PCT Article 21(2).

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent, of an international application (IA) that were filed on or after November 29, 2000 but were **not** published in **English** under PCT Article 21(2) have no § 102(e) prior art date at all. According to § 102(e), no benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was published under PCT Article 21(2) in a language other than English. Such references may be applied under § 102(a) or (b) as of their publication dates, but never under § 102(e).




The § 102(e)(1) date for the IA publication by WIPO is: None
The § 102(e)(1) date for Publication by USPTO is: None
The § 102(e)(2) date for the Patent is: None

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2002).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e) date for all the references.
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e) date of the patent or publication of the later-filed U.S. application would be the actual filing date of the later-filed U.S. application.

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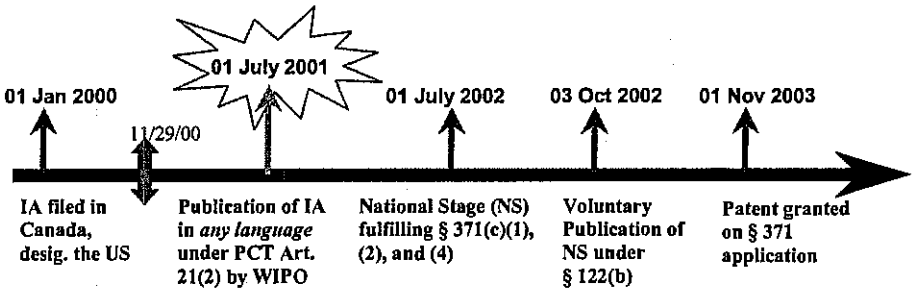
**Example 6:** References based on the **National Stage (§ 371)** of an **International Application filed prior to November 29, 2000** (language of the publication under PCT Article 21(2) is not relevant)

The reference U.S. patent issued from an international application (IA) that was filed prior to November 29, 2000 has a § 102(e) prior art date of the date of fulfillment of the requirements of 35 U.S.C. § 371(c)(1), (2) and (4). This is the pre-AIPA § 102(e). The

application publications, both the WIPO publication and the U.S. publication, published from an international application that was filed prior to November 29, 2000, do not have any § 102(e) prior art date. According to the effective date provisions as amended by H.R. 2215, the amendments to §§ 102(e) and 374 are not applicable to international applications having international filing dates prior to November 29, 2000. The application publications can be applied under § 102(a) or (b) as of their publication dates.




The § 102(e)(1) date for the IA publication by WIPO is: None
The § 102(e)(1) date for Publication by USPTO is: None
The § 102(e) date for the Patent is: 01 July 2002

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 July 2001).

Additional Priority/Benefit Claims:

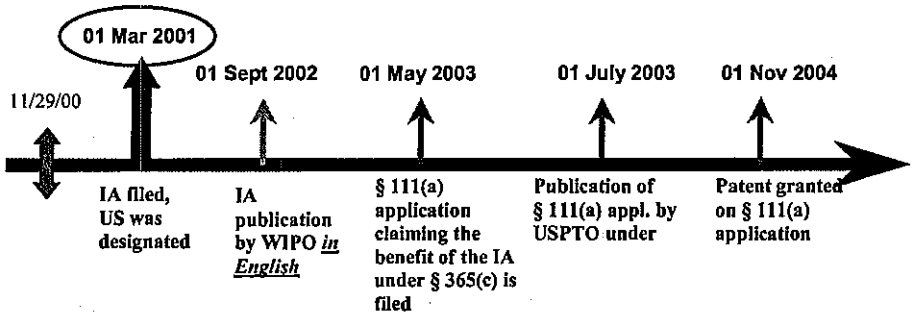
- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the U.S. and WIPO application publications, and the § 102(e) date for the patent will still be 01 July 2002 (the date of fulfillment of the requirements under § 371(c)(1), (2) and (4)).
- ✓ If a later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the IA in the example above, the § 102(e)(1) date of the application publication of later-filed U.S. application would be the actual filing date of the later-filed U.S. application, and § 102(e) date of the patent of the later-filed U.S. application would be 01 July 2002 (the date that the earlier-filed IA fulfilled the requirements of § 371(c)(1), (2) and (4)).

---

**Example 7:** References based on a § 111(a) Application which is a **Continuation of an International Application,** which was **filed on or after November 29, 2000, designated the U.S.** and was **published in English** under PCT Article 21(2)

All references, whether the WIPO publication, the U.S. application publication or the U.S. patent of, or claiming the benefit of, an international application (IA) that was filed

on or after November 29, 2000, designated the U.S. and was published in English under PCT Article 21(2) have the § 102(e) prior art date of the international filing date or earlier effective U.S. filing date. No benefit of the international filing date (nor any U.S. filing dates prior to the IA), however, is given for § 102(e) purposes if the IA was published under PCT Article 21(2) by WIPO in a language other than English.




The § 102(e)(1) date for the IA publication by WIPO is: 01 Mar 2001
The § 102(e)(1) date for Publication by USPTO is: 01 Mar 2001
The § 102(e)(2) date for the Patent is: 01 Mar 2001

Additional Priority/Benefit Claims:

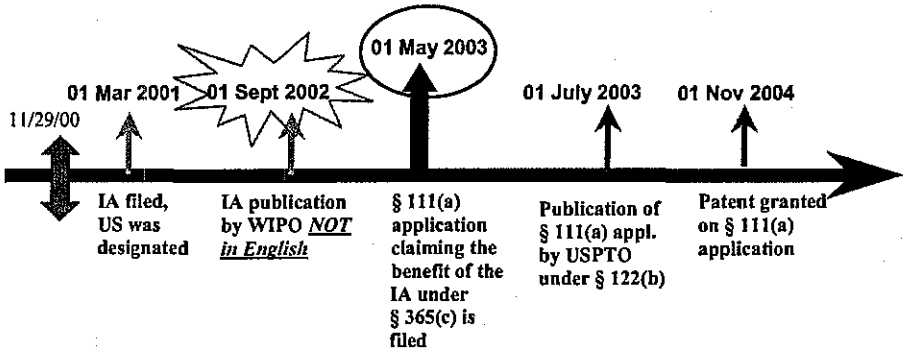
- ✓ If the IA properly claimed priority to an earlier-filed U.S. provisional (§ 111(b)) application or the benefit of an earlier-filed U.S. nonprovisional (§ 111(a)) application, the § 102(e) date for all the references would be the filing date of the earlier-filed U.S. application, assuming the earlier-filed application has proper support for the subject matter relied upon as required by §§ 119(e) or 120.
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the international filing date of the IA, assuming the earlier-filed IA has proper support for the subject matter relied upon as required by § 120.

---

**Example 8:** References based on a § 111(a) Application which is a **Continuation of an International Application**, which was **filed on or after November 29, 2000** and was **not published in English** under PCT Article 21(2)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation of an international application (IA) that was filed on or after November 29, 2000 and but **not** published in English under PCT Article 21(2) have the § 102(e) prior art date of its actual U.S. filing date under §111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) purposes if the IA was published under PCT Article 21(2) in a language other than English. The IA publication under PCT Article 21(2) does not have a prior art date under § 102(e)(1) because the IA was not

published in English under PCT Article 21(2). The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.




The § 102(e)(1) date for the IA publication by WIPO is: None
The § 102(e)(1) date for Publication by USPTO is: 01 May 2003
The § 102(e)(2) date for the Patent is: 01 May 2003

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2002).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of the later-filed § 111(a) application in the example above (01 May 2003).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of the § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 May 2003).

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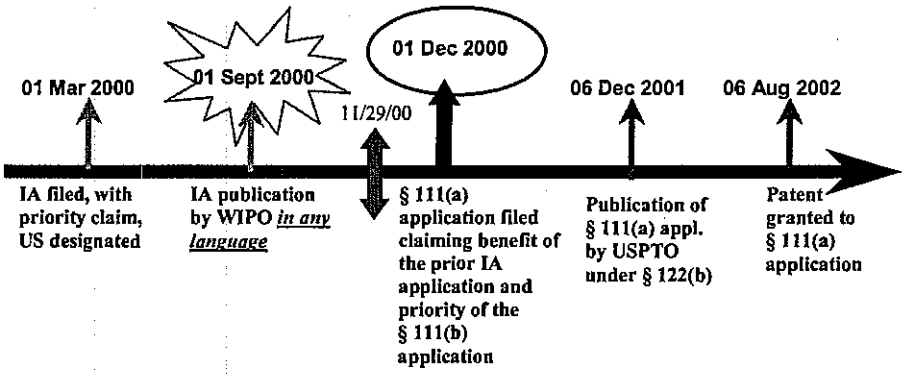
**Example 9:** References based on a § 111(a) Application which is a **Continuation** (filed prior to any entry of the National Stage) **of an International Application**, which was **filed prior to November 29, 2000** (language of the publication under PCT Article 21(2) is not relevant)

Both the U.S. publication and the U.S. patent of the § 111(a) continuation (filed prior to any entry of the National Stage) of an international application (IA) that was filed prior to November 29, 2000 have the § 102(e) prior art date of its actual U.S. filing date under §111(a). No benefit of the international filing date (nor any U.S. filing dates prior to the IA) is given for § 102(e) prior art purposes if the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) does not have a prior art date under

§ 102(e)(1) because the IA was filed prior to November 29, 2000. The IA publication under PCT Article 21(2) can be applied under § 102(a) or (b) as of its publication date.




The § 102(e)(1) date for the IA publication by WIPO is: None
The § 102(e)(1) date for Publication by USPTO is: 01 Dec 2000
The § 102(e) date for the Patent is: 01 Dec 2000

The IA publication by WIPO can be applied under § 102(a) or (b) as of its publication date (01 Sept 2000).

Additional Priority/Benefit Claims:

- ✓ If the IA properly claimed priority/benefit to any earlier-filed U.S. application (whether provisional or nonprovisional), there would still be no § 102(e)(1) date for the IA publication by WIPO, and the U.S. application publication and patent would still have a § 102(e) date of the actual filing date of later-filed § 111(a) application in the example above (01 Dec 2000).
- ✓ If a second, later-filed U.S. nonprovisional (§ 111(a)) application claimed the benefit of § 111(a) application in the example above, the § 102(e) date of the patent or publication of the second, later-filed U.S. application would still be the actual filing date of the § 111(a) application in the example above (01 Dec 2000).

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FOR FURTHER INFORMATION CONTACT: Jeanne Clark or Robert Clarke, Legal Advisors in the Office of Patent Legal Administration, by telephone at (703) 305-1622, by fax at (703) 305-1013, or by e-mail addressed to Jeanne.Clark@USPTO.gov or Robert.Clarke@USPTO.gov.

[date]

Stephen G. Kunin
Deputy Commissioner
for Patent Examination Policy

[1] If the reference is a patent based on an International Application filed prior to November 29, 2000, § 102(e) prior to the AIPA is used to determine its § 102(e) prior art date.
[2] The amendments to § 102(e) were set forth in section 4505 of the AIPA, as amended by H.R. 2215. The amendments to § 374 were set forth in section § 4507 of the AIPA, as amended by H.R. 2215.
[3] The revision to 35 U.S.C. § 103(c) was made in § 4807 of the AIPA and is applicable only to applications filed on or after November 29, 1999.

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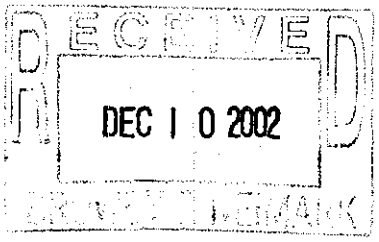


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RA - Rechtsanwalt/Attorney at Law
* - European Patent Attorney
○ - Maître en Droit
▽ - Licencié en Droit
- Diplôme d'Etudes Approfondies en Conception de Produits et Innovation
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|---|---|---|---|
| | | **Abl.** | December 3, 2002 |

Protection of Designs and Shapes in Europe

Dear Sirs,

We would like to announce a new development in European legislation which will offer interesting new possibilities for every party interested in the protection of designs and shapes. In the enclosure, please find a short introduction into the European Design Registration which will be available from April 1, 2003 with applications already possible from January 1, 2003. We would be more than pleased to assist you with any upcoming matter.

Yours faithfully
BOEHMERT & BOEHMERT
S. Herrmann
for Andreas Winkler

- 38.147 -

On 12 December 2001, the European Regulation on Community Designs was adopted. Up until now the protection of designs has been a matter for the national law of the 15 member states with a patchwork of different legislation granting different protection in each member state. Although the national laws are to be approximated, protection is limited to the territory of one member state, and it constitutes a long and costly exercise to apply for protection on a national basis.

The Regulation on Community Designs now introduces for the first time a single unified Community wide system for the protection of designs. From January 1st, 2003 on it will be possible to obtain one design right for one area encompassing the whole of the European Union by a single procedure under one law, the main features of which are as follows.

1. The Regulation defines 'design' as the appearance of a product or part of a product resulting from the features of the product itself or its ornamentation, such as the lines, contours, shape, texture and material. As there are no restrictions as to how the design comes about, the new law is relevant for all producers of goods of whichever kind and whatever appearance. However, a design cannot be registered if its appearance is solely dictated by its technical function.

2. In order to be protected a design has to be new and have individual character. A design is new if no identical design or a design differing only in minor details has been made available to the public, that is the circles specialized in the sector concerned. It has an individual character if the overall impression it produces on the informed user differs from the overall impression of any design which has previously been made available to the public. The design need not have any aesthetic quality. The only requirement is a certain difference in the overall appearance if compared to similar designs which are already known to the informed user. The threshold to be passed by a specific design to possess individual character is expected to be rather low.

3. The Regulation introduces a two-fold system of protection. Some kinds of products usually have a short market life and are of minor importance for the producer. Other products need a longer term and broader scope of protection because they are of vital interest for the producer. The various interests of the producers called for two forms of protection, the short-term unregistered design and the registered design. As both forms can protect a design, it is up to the producer to choose the form which fits his interest.

   a) The unregistered design came into existence on 6 March 2002. It is protected automatically for a period of three years after the design was made available to the public, that is the circles specialized in the relevant sector within the European Union. It confers protection against reproduction of a design by deliberate copying. Those sectors of industry producing large numbers of short-lived designs of which only a few may eventually be commercialized, may find advantage in the unregistered design because there are no costs for registration. The holder of an unregistered design must prove both that he himself has disclosed his design and that he is being copied. Unregistered

b
c

designs cannot be invoked against the independent creation of another designer who may reasonably be thought not to be familiar with the unregistered design.

b) The registered design on the other hand grants the holder the exclusive right to use the design and to prevent its unauthorized use. No other party will be entitled to use that design, even if it is created independently. The holder can prevent third parties from making, offering, importing, exporting or stocking a product in which the design is incorporated or to which it is applied. The protection commences on the date of filing, and the term of protection is five years from filing, renewable up to a maximum of 25 years. The registered design provides legal certainty and offers a longer term of protection corresponding to the foreseeable market life of the products concerned. In an infringement action the registered design has to be treated as valid. Validity can only be challenged with a counter-claim for a declaration of invalidity. It is also stronger compared to the un-registered design because it allows the holder to exclude all later creations infringing his design without proving that they are copies of his design.

   The introduction of the registered design will be delayed until next year because the implementing and fees regulations have yet to be adopted. The present draft of the implementing regulation provides for design applications to be filed from 1 January 2003 onwards, with filing dates being allocated, and hence registrations being issued from 1 April 2003 onwards.

4. The registration system is said to be kept as simple and cheap as possible in order to make registered designs readily available to small and medium-sized enterprises. Registration takes place at the European Office for Harmonization in the Internal Market (OHIM) in Alicante, Spain. There is only one application needed to receive protection throughout Europe in the same manner as the Community Trademark system currently provides for trademarks. There is no substantive examination as to compliance with the requirements for protection prior to registration.

   Important features of the Regulation will be the possibility for the applicant to defer the publication of a design and the possibility to combine a number of designs in one multiple application. By deferring the publication for up to 30 months, creators and producers can apply for protection and at the same time keep their designs secret until they are put on the market. Multiple applications are cost saving, each of the designs in a multiple application can be enforced, licensed etc. separately from the others. The OHIM has prepared a set of legal and administrative tools to allow swift and simple registration procedures.

5. The costs for filing an application for a Community Design registration mainly depend on the official filing fees which have not yet been fixed by OHIM. We will include a special tariff in a schedule of fees as soon as the OHIM publishes its official fees.

6. The enforcement of Community designs is dealt with by a limited number of Community Design Courts in the member states. Thus, legal certainty is ensured. Infringement proceedings can be brought in the courts of the member states in which the alleged infringer is domiciled. This court can deal with an infringement in any member state. Alternatively proceedings can be brought in the courts where the infringement has been committed. In this case the court has only jurisdiction in the relevant member state. The Regulation provides for some standard sanctions, namely orders to prohibit the infringer from proceeding with the infringing act and to seize the infringing goods as well as material and imple-

ments used to manufacture infringing goods. In addition other sanctions provided by national law can be imposed. There is also the possibility to apply for provisional measures and border seizures.

An action or counterclaim for the declaration of invalidity of a registered design can only be based on the grounds that it lacks novelty or individual character, that it is functional, immoral or contrary to public order, that it is registered in the name of someone who is not the proprietor or that there is a conflicting registered design with an earlier priority. Invalidation claims can only be made by application at the OHIM, or by a counterclaim at the Community Design Courts. In order to avoid invalidation proceedings it will be necessary to conduct at least research in the design register.

7. The Community design is a means to simplify the confusing variety of national rights and to grant protection throughout the European Union, which will soon comprise 25 member states. The definition of design is very broad and will ensure a wide scope of applicability for the new rights. The holders of eligible designs can make use of a simple and inexpensive procedure to register them with the OHIM and to gain stronger and longer protection for their designs. The Community Design Regulation is an important step in fighting counterfeiting and piracy.

This is only a short outline of the new legal instruments which can be used to protect your intellectual property. Boehmert & Boehmert will be happy to assist you with our experience in the application and enforcement of the Community designs.

DJ ORAL HEARING + REPLY BRIEF 12/4/06

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**browse before**

# 1208 Reply Briefs and Examiner's Responses to Reply Brief< [R-3] - 1200 Appeal

## 1208 Reply Briefs and Examiner's Responses to Reply Brief< [R-3]

**>

**37 CFR 41.41 R**

(a)

(1) Appellant m
the date of the

(2) A reply br
or non-admi
amendment
same date
evidence fi

Reminder for Reply Brief due 12/4/06 sent 11/28/06

(b) A reply brief that is ... not be considered. Appellant will be no... paragraph (a) of this section.

(c) Extensions of time under § **1.136** (a) of this title for patent appli... not applicable to the time period set forth in this section. See § **1.136** (b) of this title for extensions of time to reply for patent applications and § **1.550** (c) of this title for extensions of time to reply for ex parte reexamination proceedings.

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**37 CFR 41.43 Examiner's response to reply brief.**

(a)

(1) After receipt of a reply brief in compliance with § **41.41**, the primary examiner must acknowledge receipt and entry of the reply brief. In addition, the primary examiner may withdraw the final rejection and reopen prosecution or may furnish a supplemental examiner's answer responding to any new issue raised in the reply brief.

(2) A supplemental examiner's answer responding to a reply brief may not include a new ground of rejection.

(b) If a supplemental examiner's answer is furnished by the examiner, appellant may file another reply brief under § **41.41** to any supplemental examiner's answer within two months from the date of the supplemental examiner's answer.

(c) Extensions of time under § **1.136**(a) of this title for patent applications are not applicable to the time period set forth in this section. See § **1.136**(b) of this title for extensions of time to reply for patent applications and § **1.550**(c) of this title for extensions of time to reply for ex parte reexamination proceedings.

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## I. REPLY BRIEF

Under 37 CFR **41.41**(a)(1) and **41.43**(b), appellant may file a reply brief as a matter of right within 2 months from the mailing date of the examiner's answer or supplemental examiner's answer. Extensions of time to file the reply brief may be granted pursuant to 37 CFR **1.136**(b) (for patent applications) or **1.550**(c) (for *ex parte* reexamination proceedings). Extensions of time under 37 CFR **1.136**(a) are not permitted. The examiner may provide a supplemental examiner's answer to respond to any reply brief that raises new issues. See MPEP § **1207.05**. Normally, appellant is not required to file a reply brief to respond to an examiner's answer or a supplemental examiner's answer, and if appellant does not file a reply brief within the two month period of time, the application will be forwarded to the Board for decision on the appeal. In response to the following, however, appellant is required to file either a reply brief to maintain the appeal or a reply under 37 CFR **1.111** to reopen prosecution:

(A) An examiner's answer that contains a new ground of rejection pursuant to 37 CFR **41.39** (see MPEP § **1207.03**); or

(B) A supplemental examiner's answer responding to a remand by the Board for further consideration of a rejection pursuant to 37 CFR **41.50**(a) (see MPEP § **1207.05**). Such a supplemental examiner's answer may contain a new ground of rejection (also see MPEP § **1207.03**).

If appellant requests that the appeal be maintained in response to a new ground of rejection made in an examiner's answer or a supplemental examiner's answer, the appellant must file a reply brief to address each new grounds of rejection set forth in the answer in compliance with 37 CFR **41.37**(c)(1)(vii) within two months from the mailing of the answer. The reply brief should include the following items, with each item starting on a separate page, so as to follow the other requirements of a brief as set forth in 37 CFR **41.37**(c):

(A) Identification page setting forth the appellant's name(s), the application number, the filing date of the application, the title of the invention, the name of the examiner, the art unit of the examiner and the title of the paper (i.e., Reply Brief);

(B) Status of claims page(s);

(C) Grounds of rejection to be reviewed on appeal page(s); and

(D) Argument page(s).

The reply brief can also be a substitute brief replacing the original brief by responding to both the new ground of rejection and all other grounds of rejection covered in the original brief. In such an instance, the reply brief must meet all the requirements of a brief as set forth in 37 CFR **41.37**(c).

Any reply brief must also be in compliance with requirements set forth in 37 CFR **41.41**. New or non-admitted affidavits, and/or other evidence are not permitted in a reply brief. Any new amendment must be submitted in papers separate from the reply brief, and the entry of such papers is subject to the provisions of 37 CFR **41.33**. A paper that contains an amendment is not a reply brief within the meaning of 37 CFR **41.41**. Such a paper will not be entitled to entry simply because it is characterized as a reply brief.

If a reply brief is filed in response to a supplemental examiner's answer under 37 CFR **41.50**(a) that was written in response to a remand by the Board for further consideration of a rejection, any reply brief accompanied by an amendment, affidavit or other evidence will be treated as a request that prosecution be reopened before the examiner. If appellant fails to file a reply brief or a reply under 37 CFR **1.111** within two months from the mailing of the examiner's answer that contains a new ground of rejection, or a supplemental examiner's answer under 37 CFR **41.50**(a), the examiner will dismiss the appeal as to the claims subject to the new ground of rejection or the rejection for which the Board has remanded the proceeding. See MPEP § **1207.03** and § **1207.05**.

## II. EXAMINER'S RESPONSE TO A REPLY BRIEF

If a reply brief is not in compliance with 37 CFR **41.41**, the examiner must notify appellant that the reply brief has not been considered and the reason for non-compliance. The examiner may use form paragraph 12.182 on Form PTOL-90 to notify the appellant.

**¶ 12.182 Reply Brief Not Considered**

The reply brief filed on **[1]** has not been considered because it is not in compliance with 37 CFR **41.41**(a). The reply brief **[2]**.

**Examiner Note**

1. In bracket 1, insert the date on which the reply brief was filed.

2. In bracket 2, insert the reasoning. For example, insert "was not filed within the non-extendable time period set in 37 CFR **41.41**(a)(1)" or insert "included a new or non-admitted amendment or new or non-admitted affidavit or other evidence".

3. Use this form paragraph to notify the appellant under 37 CFR **41.41**(b) that a reply brief is not being considered because it is not in compliance with 37 CFR

**41.41**(a).

If a reply brief is filed in compliance with 37 CFR **41.41**, the primary examiner must acknowledge receipt and entry of the reply brief. The examiner may use form paragraph 12.181 on Form PTOL-90 to provide the acknowledgment.

**¶ 12.181 Acknowledgment of Reply Brief**

The reply brief filed **[1]** has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

**Examiner Note**

1. In bracket 1, insert the date on which the reply brief was filed.

2. Use this form paragraph to notify the appellant under 37 CFR **41.43**(a)(1) that a reply brief has been received and entered.

3. This form paragraph is to be printed on a blank page for attachment to a PTOL-90 or PTO-90C.

4. Include form paragraph **12.184** after this paragraph to include a supplemental examiner's answer under 37 CFR **41.43**(a)(1) responding to any new issue raised in the reply brief.

In addition, the examiner may:

(A) Withdraw the final rejection and reopen prosecution to respond to the reply brief (see MPEP § **1207.04**); or

(B) Furnish a supplemental examiner's answer responding to any new issue raised in the reply brief (see MPEP § **1207.05**).

Any supplemental examiner's answer responding to a new issue raised in a reply brief must be approved by the Technology Center (TC) Director or designee. 37 CFR **41.43**(a)(2) prohibits a supplemental examiner's answer responding to a reply brief from including a new ground of rejection. After the filing of a reply brief, any new ground of rejection responding to a reply brief must be by way of reopening of prosecution. See MPEP § **1207.04**. The examiner's decision to withdraw the final rejection and reopen prosecution to enter a new ground of rejection requires approval from the supervisory patent examiner, which approval must be indicated in the Office action setting forth the new ground of rejection. See MPEP § **1207.04**.

In response to the supplemental examiner's answer, the appellant may file another reply brief under 37 CFR **41.41** within 2 months from the mailing of the supplemental examiner's answer. The two month time period for reply is not extendable under 37 CFR **1.136**(a), but is extendable under 37 CFR **1.136**(b) for patent applications and 37 CFR **1.550**(c) for *ex parte* reexamination proceedings. Appellant cannot request that prosecution be reopened pursuant to 37 CFR **41.39**(b) or **41.50**(a) at that time.

The acknowledgment of receipt and entry of a reply brief under 37 CFR **41.41** is an indication by the examiner that no further response by the examiner is deemed necessary. It should also be noted that an indication that certain rejections have been withdrawn as a result of the reply brief is not, by itself, a supplemental examiner's answer and is permitted. Such an indication of a change in status of claims would not give appellant the right to file another reply brief. The examiner may make the indication on form PTOL-90.<

**browse after**

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Last Modified: 12/07/2005 06:34:50

Go to **MPEP - Table of Contents**

**Norman Latker**

**From:** bounce-2866-2976@listserver.techno-l.org on behalf of Ed Suominen [ed@eepatents.com]
**Sent:** Wednesday, April 26, 2006 2:00 PM
**To:** techno-l@techno-l.org
**Subject:** Re: [techno-l] University Licensing portal

In my view, the portal idea is built on the common old myth that you can "build a better mousetrap and the the world will beat a path to your door."

The sad reality appears to be that you can build a mousetrap that exceeds the world's wildest expectations and no one will pay any attention to you. Instead, you will have to spend a lot of time beating a path to the door of everyone else.

First, you will knock on the doors of prospective licensees and be told that your mousetrap is really very nice but they aren't interested because it was Not Invented Here. Then, when someone finally decides that they are going to use your mousetrap without a license (whether due to innocent ignorance of your patent or willful infringement), you will wind up beating a path to your lawyer's door.

And if too many inventors of better mousetraps are successful at actually enforcing their patents, you can rest assured that the whole mousetrap industry will be beating a path to the doors of Congress and the USPTO.

Best regards,
Ed Suominen
U.S. Patents 6,904,405; 6,631,256; 6,427,068; 6,052,748; 5,937,341, plus applications pending.

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E-MAIL
mail@browdyneimark.com

September 5, 2007

Congressman Chris Van Hollen
1707 Longworth H.O.B.
Washington, DC 20515

Re: (1) The new Patent Legislation
(2) The Patent and Trademark Office

Dear Congressman Van Hollen:

I have been an Intellectual Property professional now for almost 50 years, beginning in 1956 as a patent examiner at what was then the United States Patent Office. Never have I seen such a sad state of affairs with respect to the patent system and the U.S. Patent and Trademark Office (PTO).

The patent system may seem inconsistent with liberal philosophy, but it is not. Permit me to explain the importance of the patent system through a quote from a little known book entitled "The Patent Office Pony" which provides a history of the early United States Patent Office:

> In early 1886, the Japanese government sent Korekiyo Takahashi (1854-1936), soon to be their first Commissioner of Patents, to Washington to study the U.S. Patent Office.....
>
> Among the many patent examiners who had discussions with Mr. Takahashi was ... Dr. P. B. Pierce,.... Near the end of these discussions, Dr. Pierce said: "Mr. Takahashi, I have answered many questions asked by you; would you object to

> answering a single question which I would like to put to you?.... I would like to know why it is that the people of Japan desire to have a Patent system."
>
> "I will tell you, then," said Mr. Takahashi. "You know that it is only since Commodore Perry in 1854, opened the ports of Japan to foreign commerce that the Japanese have been trying to become a great nation, like other nations of the earth, and we have looked about us to see what nations are the greatest, so that we could be like them; and we said 'there is the United States, not much more than 100 years old, and America was discovered by Columbus yet 400 years ago;' and we said 'what is it that makes the United States such a great nation?' and we investigated and we found that it was patents, and we will have patents."

I hate to see a great system destroyed by poor legislation and mismanagement by the incompetents who are presently running the Patent and Trademark Office.

Very frankly, the effects of the proposed legislation will be bad enough, mostly to the benefit of the largest companies and to the detriment of small companies, individual inventors, and universities and other not-for-profit research centers; but the changes being effected within the PTO, scheduled to become effective November 1 of this year, and I believe without statutory authority, are even worse. The new rules package will make patent prosecution even more onerous and accordingly more expensive. Many inventions which could benefit society will not reach the light of day.

It is perfectly predictable that passage of the legislation and implementation of the PTO changes will eventually end this country's recognized world leadership in the introduction of new technology to the detriment of our economy and well-being.

Congress should do two things. First, it should not pass the new patent legislation. Second, it should investigate the PTO. It is very important that the congress recognize the fundamental importance of this issue. In this regard, please consider

contacting our major universities and NIH, all of which have relied on our patent system to achieve commercial introduction of government funded inventions for the last 25 years.

Thank you for considering my views.

Sincerely,

Norman J. Latker
5112 Edgemoor Lane
Bethesda, MD 20814

NJL:ma
G:\NJL\Misc\2007-09-05 Congressman Chris Van Hollen Ltr.doc

MR. LATKER

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E-MAIL
BrwdyNmrk@digizen.net

PATENT AGENT
ALLEN C. YUN, PH.D

October 30, 1998

**VIA TELEFACSIMILE**
**URGENT**

Mr. Hideo Okazaki
OKAZAKI PATENT OFFICE
502 Ando Building
Ikebukuro 2-11-9
Toshima-ku, Tokyo
JAPAN

Re: Masashi MAEDA - USSN 08/947,199
FISHING ROD
Your Reference: HT 9045
Our Reference: MAEDA=7

Dear Mr. Okazaki:

Faxed herewith is a copy of pages 2 and 3 only of a restriction requirement mailed October 16, 1998. A complete copy accompanies the confirmation copy of this report.

Looking at the attached page 2, you will see that the examiner considers that the claims are directed to three (3) patentably distinct species respectively identified as Groups I, II and III, as follows:

Group I, Figs. 2-4;
Group II, Figs. 5-6; and
Group III, Fig. 7

In the usual way, we are required to elect only one of the three (3) groups for further prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. The Examiner has identified claim 1 as being generic. The requirement may be traversed, but the election must still be made. If you do wish for us to traverse the requirement, please provide us with reasons. Also please identify the claims which read on the elected species.

If the election is made without traverse (or with traverse, but the traversal is ultimately unsuccessful as usually occurs), then the claims as directed to the non-elected groups will be

withdrawn from consideration and not examined. However, if a generic claim is not allowed and if it is desired to continue prosecution on either or both of the non-elected groups, this can be done by filing one or two divisional applications.

A shortened term for response has been set to expire in only thirty days, i.e. the due date is November 15, 1998. Please let us have your instructions sufficiently soon so that we can meet this due date, preferably by

**November 9, 1998.**

Thank you. We await hearing from you. Our debit note for services is attached to the confirmation copy of this report.

Sincerely,

Norman J. Latker
Managing Attorney

NJL:ndh
Enclosures
f:\nina\njl\mae17rst.ltr

FORM CD-183
(REV.2-80)
FORMERLY SEC-350

U.S. DEPARTMENT OF COMMERCE

## ABSTRACT OF SECRETARIAL CORRESPONDENCE

NOV 25 REC'D

| TO: | X | The Secretary | | The Deputy Secretary |
|---|---|---|---|---|

Date: NOV 21 1986

FILE

DECISION MEMORANDUM

From: Under Secretary for Economic Affairs

Prepared by: Norman J. Latker/EA/OPTI/377-0659

SUBJECT Implementation of the Federal Technology Transfer Act

STATEMENT OF THE ISSUE

What steps should the Department take to implement the Federal Technology Transfer Act of 1986?

ANALYSIS

On October 20, the President signed the Federal Technology Transfer Act of 1986 (P.L. 99-502), which amends the Stevenson-Wydler Act (P. L. 96-480). Commerce supported this Act as priority legislation. It builds on fundamental principles the Department developed for managing technology produced with Federal funding. The principles, which we have embodied in two previous laws and the President's Patent Policy Memorandum, give universities and businesses control of their technology and strong incentives to promote its commercial application. This Act finally extends these principles to Government-operated laboratories and, if implemented properly, can give U.S. industry practical access to nearly all unclassified technology the Government funds or produces in the laboratories.

Among the amendments are provisions that promote technology transfers by permitting agencies to authorize Government-operated laboratories to enter into cooperative research and development arrangements or licensing agreements with the private sector, subject to statutory or agency imposed conditions. The amendments also provide needed incentives

Control No. 625079

| | NBS | PTO | | Malcolm Baldrige |
|---|---|---|---|---|
| | EA 12/5 | DQ 12/8 | HWR | DEC 10 1986 |

| | PREPARED BY | CLEARED BY | CLEARED BY | CLEARED BY | CLEARED BY | CLEARED BY |
|---|---|---|---|---|---|---|
| SURNAME AND ORGANIZATION (Typed) | DBMerrifield A/S, PTI | REllert Ch.C/EA | ES | Admin | [illegible] | I+A |
| INITIALS AND DATE | [illegible] 11/12 PC | [illegible] 11/17 | PC 12/9 | KB 12/3 | RHB 11/26 | JMF 12/4 |

Rec'd 12/3 Rec'd 12/9

COMM-DC 1030-P80

to encourage laboratories and their scientists to examine how the results of projects funded to meet Federal needs might be adapted to commercial uses. It does this by permitting the laboratories to accept resources from the private sector under cooperative arrangements and by assuring laboratory scientists a percentage of the royalties resulting from their inventions.

From its beginning, the Administration has been striving to increase American innovation by decentralizing the management of technology coming out of Federally supported programs. The Administration's policy is widely supported in the private sector. It is viewed by state and local governments as a centerpiece of local economic development. In order to take full advantage of this unique opportunity to broaden the U. S. technology base, the department must now move forcefully to implement the President's policy.

Within the Department of Commerce the technology transfer function contained in this new Act are the programmatic responsibility of the Under Secretary for Economic Affairs. Accordingly, as a first step in implementing the Technology Transfer Act of 1986, the additional agency level and Government-wide coordinating authorities vested in you by these new amendments to the Stevenson-Wydler Act should be delegated to the Under Secretary for Economic Affairs.

When this delegation has been made, we will create a DoC committee to implement the Technology Transfer Act of 1986, of all interested Departmental units in order to expedite implementation within the Department. The committee would undertake as a primary task the further delegation of the cooperative arrangement and licensing authorities to Commerce laboratories under appropriate conditions.

RECOMMENDATIONS

1. I recommend that you delegate the authorities and responsibilities given you under these new amendments to the Stevenson-Wydler Act to the Under Secretary for Economic Affairs. (Attached at tab A is a summary of the authorities to be delegated to the Under Secretary for Economic Affairs. Also attached at tab B is a copy of Public Law 99-502, with the new authorities to be delegated underlined in red). If you agree with this proposed delegation, we will coordinate with the Assistant Secretary for Administration to amend the appropriate Departmental Orders.

DECISION

Approve √ Disapprove_____ Let's Discuss_____

DEC 10 1986

2. I recommend your approval of the establishment by the Under Secretary for Economic Affairs of a DoC committee to implement the Technology Transfer Act of 1986.

DECISION

Approve ✓ Disapprove_____ Let's Discuss _____

DEC 10 1986

# COORDINATING AUTHORITIES CREATED BY P. L. 99-502

## I. Government-wide Coordinating Authority Assigned to the Commerce Department by P. L. 99-502

Section 10(g)(1)

The Secretary, in consultation with other Federal agencies, may--

(A) make available to interested agencies the expertise of the Department of Commerce regarding the commercical potential of inventions and methods and options for commercialization which are available to the Federal laboratories, including research and development limited partnerships;

(B) develop and disseminate to appropriate agency and laboratory personnel model provisions for use on a voluntary basis in cooperative research and development arrangements; and

(C) furnish advice and assistance, upon request, to Federal agencies concerning their cooperative research and development programs and projects.

Section 10(g)(2)

Two years after the date of the enactment of this subsection and every two years thereafter, the Secretary shall submit a summary report to the President and the Congress on the use by the agencies and the Secretary of the authorities specified in the Act...

Section 10(g)(3)

Not later than one year after the date of the enactment of the Federal Technology Transfer Act of 1986, the Secretary shall submit to the President and the Congress a report regarding--

(A) any copyright provisions or other types of barriers which tend to restrict or limit the transfer of federally funded computer software to the private sector and to State and local governments, and agencies of such State and local governments; and

(B) the feasibility and cost of compiling and maintaining a current and comprehensive inventory of all federally funded training software.

## II. Agency-level Coordinating Activities Created by P. L. 99-502

### A. Cooperative Agreements

Section 11(a)

Each Federal agency may permit the director of any of its Government-operated Federal laboratories--

(1) to enter into cooperative research and development agreements on behalf of such agency (subject to subsection (c) of this section)..., and

(2) to negotiate licensing agreements...

Section 11(c)(1)

A federal agency may issue regulations on suitable procedures for implementing the provisions of this section...

Section 11(c)(3)(A)

Any agency using the authority given it under subsection (a) shall review employee standards of conduct for resolving potential conflicts of interest...

Section 11(c)(3)(B)

If...an agency is unable to resolve potential conflicts of interest within its current statutory framework, it shall propose necessary statutory changes to be forwarded to its authorizing committees in Congress.

Section 11(c)(5)(A)

If the head of the agency...desires an opportunity to disapprove or require the modification of any such agreement, the agreement shall provide a 30-day period within which such action must be taken beginning on the date the agreement is presented to him or her by the head of the laboratory concerned.

Section 11(c)(5)(B)

In any case in which the head of an agency... disapproves or requires the modification of an agreement..., the head of the agency...shall transmit a written explanation of such disapproval or modification to the head of the laboratory concerned.

B. Awards Program

Section 12

The head of each Federal agency that is making expenditures at a rate of more than $50,000,000 per fiscal year for research and development in its Government-operated laboratories shall...develop and implement a cash awards program to reward its scientific, engineering, and technical personnel for--

(1) inventions, innovations, or other outstanding scientific or technological contributions of value to the United States due to commercial applications or due to contributions to missions of the Federal agency or the Federal Government, or

(2) exemplary activities that promote the domestic transfer of science and technology development within the Federal Government and result in utilization of such science and technology by American industry or business, universities, State or local governments, or other non-Federal parties.

C. Distribution of Royalty Income

Section 13(a)(1)

Except as provided in paragraphs (2) and (4), any royalties...received by a Federal agency from the licensing or assignment of inventions...shall be disposed of as follows:

(A)(i) The head of the agency...shall pay at least 15 percent of the royalties...to the inventor....This clause shall take effect on the date of the enactment of this section unless the agency publishes a notice in the Federal Register within 90 days of such date indicating its election to file a Notice of Proposed Rulemaking pursuant to clause (ii).

(A)(ii) An agency may promulgate... regulations providing for an alternative program for sharing royalties with inventors...

Section 13(a)(1)(A)(iii)

Any agency that has published its intention to promulgate regulations under clause (ii) may elect not to pay inventors under clause (i) until the expiration of two years after the date of the enactment of this Act or until the date of the promulgation of such regulations, whichever is earlier. If an agency makes such an election and after two years the regulations have not been promulgated, the agency shall make payments (in accordance with clause (i)) of at least 15 percent of the royalties involved, retroactive to the date of the enactment of this Act. If promulgation of the regulations occurs within two years after the date of the enactment of this Act, payments shall be made in accordance with such regulations, retroactive to the date of the enactment of this Act. The agency shall retain its royalties until the inventor's portion is paid under either clause (i) or (ii)...

Section 13(a)(1)(B)

The balance of the royalties...shall be transferred by the agency to its Government-operated laboratories, with the majority share of the royalties... going to the laboratory where the invention occurred...

Section 13(a)(2)

If, after payments to inventors under paragraph (1), the royalties received by an agency in any fiscal year exceed 5 percent of the budget of the Government-operated laboratories of the agency for that year, 75 percent of such excess shall be paid to the Treasury of the United States and the remaining 25 percent may be used or obligated for the purposes described in...paragraph (1)(B) during that fiscal year or the succeeding fiscal year. Any funds not so used or obligated shall be paid into the Treasury of the United States.

Section 13(a)(4)

A Federal agency receiving royalties...as a result of invention management services performed for another Federal agency or laboratory...shall retain such royalties...to the extent required to offset the payment of royalties to inventors under...paragraph 1(A), costs and expenses incurred under clause (i) of paragraph (1)(B), and the cost of foreign patenting....All royalties...remaining after payment of... royalties, costs, and expenses... shall be transferred to the agency for which the services were performed...

D. Record Keeping

Section 11(c)(6)
Each agency shall maintain a record of all agreements entered into under this section.

Section 13(c)(1)
In making their annual budget submissions Federal agencies shall submit...summaries of the amount of royalties...received and expenditures made... under this section.

E. Federal Laboratory Consortium

Section 10(e)(1)
There is hereby established the Federal Laboratory Consortium for Technology Transfer...which, in cooperation with Federal laboratories and the private sector, shall--
(E) utilize...the expertise and services of...the Department of Commerce...,as necessary.

Section 10(e)(2)
...The representatives to the Consortium shall include...a representative appointed from each Federal agency with one or more member laboratories.

Section 10(e)(7)(C)
The heads of Federal agencies...may provide such additional support for operations of the Consortium as they deem appropriate.

published 1990 in AUTM JOURNAL

# A Win-Win Philosophy for Technology Management

Norman Latker[1]

In 1690, John Locke asserted that constitutional government could only be effective and legitimate if it recognized and preserved the natural rights of man including the right to life, liberty, and property. This was crystallized by his belief that "a man has a right to what he hath mixed his labor with." Locke's proposition is widely understood to be the underpinning of our Constitution. Locke's writings further made clear that he broadly construed property to mean virtually the entire personal sphere of what is a man's own, *including his ideas.* This principle was specifically manifested in our constitution by the grant of power to the Congress to secure for limited times to authors and inventors the exclusive right to their respective writings and discoveries. Congress' enactment of the patent and copyright laws demonstrated its belief that the right to own intellectual property is a right of man and a necessary element for successful constitutional government and the promise of prosperity envisioned for such governments. Similarly, all state laws protect the right of individuals to maintain trade secrets.

Neither the Constitution nor the respective implementing laws guarantees any right to the employers of such authors or inventors. The failure to address the rights of employers is not surprising because in 1787 writers and inventors were in most part self-employed. But as that fact changed, the common law addressed the relationship between employers and employees by upholding the assignment of a person's ideas as a condition of employment. This evidently was based on the belief that employers and their prospective employees were on an equal footing at the time of hiring, and there were no overriding national issues which need interfere with their freedom to contract. This seemingly logical rule of law eliminated any future need on the part of employers to examine whether it was equitable or desirable company or social

---

[1] Norman Latker is Vice President, Legal and Technology Affairs, University Science, Engineering and Technology, McLean, VA 22102; he was formerly Director, Office of Federal Technology Management, Department of Commerce and Patent Counsel, Department of Health, Education & Welfare.

policy to require the assignment of ideas solely as a condition of being employed. No further consideration was given to the fact that such ideas were not yet made and could not be evaluated to determine their future value to society. It does seem clear, however, that given a possibility of equal footing, the law intended that employees would negotiate for a value "in what he hath mixed his labor with." But as time passed, it became evident that employees would not achieve such footing.

It was in the context of this right in employers (including its acceptance and application by the federal government) coupled with the growth of large private and public organizations and the concentration of research funding in these organizations that the rights of authors and inventors faded into obscurity in the 1950's and 60's. Interestingly, at the same time the public perception of these organizations became increasingly critical. It seems appropriate to suggest that as latter day Edisons and Westinghouses became obscure within these organizations, the public lost its ability to relate to the organizations' achievements and began focusing on their problems.

Indeed, Congress later refused to join business (other than small business) to Bayh-Dole because of the near universal requirement for assignment of ideas of employees without additional remuneration as a condition of employment.

It was within this environment that the leadership of the Society of University Patent Administrators (SUPA) began a long struggle to gain control of ownership of inventions made with public research funding. This undertaking was driven by the understanding that successful application of university technology by industry must be a win-win situation aimed at mutual respect in which all participants, including industry and the inventor must benefit equitably from the result. From the beginning it was understood that any return from industrial licensing must be shared with the inventors that produced it based on predetermined agreement.

Victories in the executive branch came in the late 60's at the Department of Health, Education and Welfare, then in the early 70's at the National Science Foundation, but impending reversal at HEW in 1977 and intransigent bureaucratic resistance made it clear that strong university technology management offices could not be built on the shifting sands of executive policy.

Perseverance of the SUPA leadership finally delivered the Bayh-Dole Act of 1980 and through it later a coherent government policy aimed at further decentralizing technology management by permitting all federally funded creating organizations and their investigators, first at universities and then at federal laboratories, to own and benefit from the application of their technology.

Well ... principles are fine, but there will always be people who legitimately question whether they work in practice. There are a number of items that lead to the conclusion that the principles embodied in Bayh-Dole are working better than even its advocates expected.

In their last report on Bayh-Dole, the GAO indicated that in addition to increased university invention reporting and licensing, the funding of cooperative arrangements between universities receiving federal R&D funds and industry has grown 74 percent from $227 million in FY 1980 to $482 million in FY 1985 (in constant dollars). Average private funding of universities has risen to between 6 to 8 percent.

The University of Minnesota study, "University Patents Issued in 1987," verifies that invention reporting has dramatically increased: Over 900 patents issued to universities in 1987. That is four times the 230 patents that issued in 1976!

Nineteen seventy-six was the last year in which the Department of Commerce collected statistics on patents issued to federally funded research performers. In that year, the total number of patents issued for all federally funded research performers regardless of their ownership was approximately 1800 and was headed down on the basis of the trend set by the prior five years. There is no evidence that, for performers other than the universities, the statistics reversed after 1976. In fact, a report by the Patent and Trademark Office in February 1988 suggests that they still may be declining.

But presuming that since 1976 they remained flat for other performers, the total number of patents issued in 1987 for all federally funded performers would be approximately 2500, including the 900 attributed to universities. That makes the university portion 36 percent of the total, which means that university research, with approximately 10 percent of the

federal R&D budget, is producing over a third of the resulting patents. Even more fantastic is the fact that unlike the other performers this is being done at virtually no cost to the taxpayer. Further, the fact that the patents are being paid for by the universities or its licensees also suggests that they are patents that were filed after careful consideration. Can there be much question that the incentives of Bayh-Dole have worked?

Although we can be genuinely encouraged by these statistics, the report from the Patent and Trademark Office is not bright. Of the 90,000 patents issued in 1987, 47 percent went to foreign nationals, up from 45 percent in 1986. This marks a continuation of a trend that has seen the overseas share of American patents double over the past 20 years while the number of patents going to American nationals has remained static. Patents received by U.S. citizens have been steadily falling from a high of over 50,000 in 1972 to below 40,000 in 1985. At the same time scientific papers published by industrial employees slipped from 12,200 in 1973 to 10,400 in 1980. Yet R&D budgets grew 80 percent to about $52 billion from 1975 to 1985. With increasing expenditures and decreasing output, the OTA concludes that American R&D is exhibiting all the classic signs of declining productivity.

But in the midst of this industrial gloom a glimmer of hope comes from the current trend to restructure corporate America. One of the principal lessons of restructuring, just about everyone agrees, is that an experienced operating manager given the right guidance, liberal incentives, and enough freedom, can almost invariably do a better job generating value from a business than someone from corporate headquarters. So the lessons of decentralizing are also being undertaken by business. If these liberal incentives lead to better policies on remunerating their employed inventors, Bayh-Dole suggests their statistics on patents will surely improve. I think start-up companies already understand the need to take care of their inventors.

Washington still has a significant number of people hoping to manage the next big science project. Each project is supported as the answer to our competitiveness problem. "Mr. President, fund this one and we promise you that the byproducts that will result will vault us ahead of foreign competition in any area of technology touched by the project." But the past has shown that those who gain control of the funding demand control of resulting technology on grounds that inability to direct the

actions of the creator will impact on the funder's targeted result.

The members of SUPA have learned that it is possible and probably imperative to address both the directed and the serendipitous results of science. Indeed, the serendipitous result could be the initial step to a technology of greater importance to society than the directed or funded result. The most common problem of large research programs has been the lack of understanding at the funding level on how to manage serendipitous results. Bayh-Dole responds directly to that problem. In fact, the state of the art in technology management has advanced to the point where it is legitimate to challenge the funding of science projects that will not be managed by agencies under Bayh-Dole principles. The projects that immediately come to mind are the Superconducting Supercollider and Mapping the Human Genome, both of which are advocated by the Department of Energy.

If I have not made my point, I believe this last story demonstrates it. A few weeks ago a friend called at the request of his son, who is a computer scientist at one of the major universities. My friend's son wanted me to know that with the assistance of his university he had just concluded the licensing of a software program he designed for a significant return and on the basis of this he has decided to reject a job offer from a major company. He felt that the opportunity to pursue his own research to completion and still share in the value created was something that could not be met by the offer.

Louis Pasteur probably said it best:

> There is no greater charm for the investigator than to make new discoveries, but his pleasure is heightened when he sees that they have a direct application to practical life.

It seems to me that when all our creative people are treated with respect through sharing with them the return on what they have created, we will have switched on a power that no foreign competitor can equal. But, in the meantime, John Locke clearly lives here.

**Norman Latker**

**From:** RJ Riley (PIA) [rjr@piausa.org]
**Sent:** Tuesday, August 19, 2008 2:27 PM
**To:** Norman Latker
**Subject:** From Ron Riley

Ronald J. Riley,

Speaking only on my own behalf.
Affiliations:
President - www.PIAUSA.org - RJR at PIAUSA.org
Executive Director - www.InventorEd.org - RJR at InvEd.org
Senior Fellow - www.patentPolicy.org
President - Alliance for American Innovation
Caretaker of Intellectual Property Creators on behalf of deceased founder Paul Heckel
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# TELEFAX CONTROL SHEET

SENT TO: Ron Riley

DATE SENT: 8/19/08

SUBJECT: Inventors

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks:

Ron
Enclosed are two presentations. One I gave in 1990 after leaving the government and the other by Sen. Bayh in 2006. I hope you have time to look them over.

Norm

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# Bayh-Dole: Don't Turn Back The Clock

*By Senator Birch Bayh**

*Speech of Birch Bayh at the Licensing Executives Society 2006 Annual Meeting, New York, New York Tuesday, September 12, 2006*

After a quarter century of what by most objective standards has been an exceptional success, the Bayh-Dole law is under increasing attack today. Most of the attacks have come from individuals who have little experience with the comprehensive nature of how the law is implemented. They do not know what Bayh-Dole does and does not do, and why certain features were incorporated into the law. Equally important, these nay-sayers have no appreciation for the factors that motivated our efforts to develop this legislation in the first place. Most unfortunate of all, these modern-day experts in technology transfer apparently do not understand the basic factors upon which our nation's free enterprise system is based.

Bayh-Dole didn't just happen. Although both of these Senators provided leadership, let me emphasize that our success depended upon countless individuals who had a working knowledge of university research, patent law and basic economic motivators.

Permit me to give you a behind the scenes view of the genesis of Bayh-Dole. This is important because the better we understand the process which led to this law, the better we are able to deal with today's critics. First, a basic premise on which we, as Americans, have relied.

Historically, American economic success has depended upon our ability to develop creative and innovative minds whose ideas serve as the catalyst for business and industry. Free and open competition has resulted in generation after generation of increasingly sophisticated technology. With this innovation came new products followed by more and better paying jobs, increased family incomes and opportunities for home ownership. We had problems, but we were the envy of the rest of the world.

Unfortunately, we had begun to take our quality of life and our economic dominance for granted. By the early 1970's, America began to lose its technological advantage:

- We had lost our number one competitive position in steel and auto production. In a number of industries we weren't even no. 2.
- The number of U.S. patents issued each year had declined steadily since 1971.
- From 1973-1978, the number of patents granted to non-citizens had increased 35%.
- Investment in research and development over the previous 10 years had been dormant.
- American productivity was growing at a much slower rate than that of our free world competitors.
- Small businesses, which had compiled a very impressive record in technological innovation and which had provided most of the new jobs, were receiving a smaller percentage of Federal research and development money.
- The number of patentable inventions made under federally supported research had been in a steady decline.

The bottom line of these alarming economic indicators was that the United States was losing its technological edge. Frankly, the problem was so enormous and complex I doubted if there was anything I could do. It seemed hopeless and I assume that most of my colleagues shared my frustration. I felt like Moses in the wilderness and doubted if the "Man upstairs" would send down a lightening bolt.

The first step out of the wilderness began with a call to my office in the summer of 1978 from Ralph Davis, head of technology transfer at Purdue University. Like Indiana and many other universities, Purdue was making cutting edge discoveries from research funded by federal dollars. But Ralph said that the Government's policy that prohibited universities from owning these patents and leasing them to businesses killed the incentives necessary for innovative companies to fully develop these new ideas. If a company couldn't own the patent, it would not invest in developing it.

I asked Joe Allen, one of my legislative staffers, to check this out. He discovered that although the U.S. government owned approximately 28,000 patents, less than 4 percent were licensed to industry. The others were gathering dust at the Patent and Trademark Office. All those new ideas were gathering dust. The taxpayers

*Birch Bayh is a former Senator from Indiana who co-authored the Bayh-Dole Act, which revitalized the nations patent system and helped create the biotechnology industry by spawning a whole generation of scientist-entrepreneurs. Currently, Senator Bayh is a partner in the Washington, D.C. law firm of Venable LLP. E-mail: bbayh@venable.com*

were getting nothing.

Next, Joe and I met in my office with Ralph Davis and two of his associates, Howard Bremer, Director of the University of Wisconsin Alumnae Research Foundation, and Norman Latker, Patent Counsel at HEW. The collective vision of these three individuals was critical to our success. After hours of thinking through the problem, our meeting resulted in the drafting of legislation designed specifically to take advantage of the innovation found on campuses and the entrepreneurial skills of small businesses. I asked Bob Dole, the Senator from Kansas, to join in and the battle began. While Bob and I didn't always see eye to eye, we did agree that the United States could no longer afford to waste billions of dollars on university and small business research with no return on the investment.

The legislation was straight forward and easy to understand. Universities and small businesses would retain ownership of the ideas they developed through government funded research. They could license such patented ideas to industry at large for commercialization and would receive royalties. The inventors, usually professors, also received a share of the royalties if they assisted in developing the patent to market.

The Bayh-Dole bill was introduced and the legislative journey began. It was far from a cake walk. As could be expected, there were several hurdles in our way.

First, Senator Russell Long, Chairman of the powerful Senate Finance Committee, told Joe Allen, "This is the worst bill I've ever seen." Senator Long believed if the taxpayers funded any of the research, the government should have total ownership of the ideas produced. He believed he was protecting the taxpayer. But the Long theory ignored the fact that many of the resulting inventions were at a very embryonic stage of development. They required substantial expenditures before they actually became a product or applied system of benefit to the public.

Senator Long was one of the most influential members in the Senate. Among 100 equals, Russell Long was more equal than the others. He was a good friend and I had hoped to get his support. But, he'd made up his mind, he was protecting the taxpayers. The task of getting Bayh-Dole would be uphill all the way.

The second hurdle was Admiral Hyman Rickover, father of the nuclear navy. He called me at home one evening and came straight to the point. "Senator, that patent bill of yours threatens to destroy the nuclear navy. You must withdraw it immediately." He demanded to testify, and echoed Senator Long's opposition.

"In my opinion, government contractors–including many small businesses and universities–should not be given title to inventions developed at government expense...These inventions are paid for by the public and therefore should be available for any citizen to use or not as he sees fit.

"I was able to develop nuclear power systems for the navy without having had to give up property rights."

Bayh-Dole provides that the Navy and other governmental entities will have first call on patents developed by government research if they are needed. In addition, it should be understood that the nuclear navy was developed by utilizing tax dollars in its development. Private investment was not necessary for development. More to the point, the Rickover logic ignores the fundamental economics of bringing an idea or product to market from the private sector. It is estimated that for every dollar's worth of academic research which leads to a patent, it requires $10 to $10,000 (sometimes close to $1 million) of private capital to develop it and bring it to market. Far from getting a free lunch, companies that license ideas from universities often wind up paying over 99 percent of the innovation's final cost, without which the idea would have no value.

Nevertheless, there they stood, Senator Long and Admiral Rickover. A long tough battle would follow.

We were able to overcome such formidable opposition by relying on our allies on the campuses across the country and by developing strong support among the small business community nationwide. We organized task forces composed of individuals from both groups (universities and small businesses) and directed them to talk to their individual Senators and Congressmen. They did just that. Don't let anyone tell you that determined individuals can't make a difference.

To illustrate the power of this combination of citizens, I remember one afternoon when I was at my desk on the Senate floor, and an excitable Joe Allen came bounding up to report some good news. "Senator, we just got two more sponsors. Senators Kennedy and Thurmond just signed on."

Well, getting Ted Kennedy and Strom Thurmond to agree on anything was an achievement, but I couldn't help but kid Joe by asking, "Joe, are you sure this bill makes sense?" Bayh-Dole passed the Senate by the vote of 91 to 4. Those dedicated individuals had made a difference.

The Bayh-Dole bill moved to the House of Representatives. Rep. Bob Kastenmeier of Wisconsin was Chairman of the House Judiciary Subcommittee with jurisdiction over patents and trademarks. Congressman Kastenmeier was sponsoring a Carter Administration bill which was a more traditional measure for patent law reform. Our team went to work and through Howard Bremer's efforts, individuals at the University of Wisconsin explained to Rep. Kastenmeier the benefits to be derived from Bayh-Dole. In addition they pointed out to the Congressman the positive impact Bayh-Dole could

have in his district. In a matter of days, we agreed to join Congressman Kastenmeier's legislation and Bayh-Dole in one package which quickly passed the House and was sent back to the Senate for its concurrence. Congressman Kastenmeier's leadership was crucial to our success. Once again, a few individuals made a difference.

This was not the end of the story. 1980 was an election year. With Members anxious to go home and campaign, Congress recessed, planning to come back after the election for a lame duck session to take up the Budget Bill and certain other bills. Bayh-Dole was one of those. The Senate needed to agree to changes made to the bill in the House.

When Congress reconvened for the lame-duck session, as a result of the Ronald Reagan landslide, 12 Democratic Senators had been replaced by Republicans. The people of Indiana had said, "Bayh, stop making law and start practicing it." On January 3, I would be out of a job.

But, Bayh-Dole was paramount on my mind. The lame-duck session would be short, with only a few days for us to finish our task. What would Senator Long do? Our campus and small business allies had been communicating with their Senators, but Senator Long had put a hold on our bill. If he persisted, the rules of the Senate would enable him to stop us.

While we were wondering, on the last day of the 1980 session, Senator Long's legislative director cornered Joe Allen on the Senate floor and asked, "Does Senator Bayh really wanted that crazy patent bill?" Joe's answer was an emphatic yes.

Later that afternoon, I got a phone call from my friend, Russell Long. After commiserating with me at length over the outcome of the election, he paused and said, "Oh, by the way, Birch, take the vote on that damn patent bill. You've earned it. We'll miss you in the Senate." Click.

Now, fast forward 25 plus years. Here are what some of the critics are saying. I purposefully omit any attribution to avoid embarrassing the authors of such short-sighted and ill-founded criticism.

1. Universities and their researchers should not be entitled to financial reward because they are not manufacturing anything. Response: This suggests that the ideas (that is, the intellectual property) has no value. This is as ridiculous as suggesting that the manufacturing process has no value. Bayh-Dole recognizes that the idea alone has no value. It is designed to create the incentive for entrepreneurs to invest in the idea and provide the development capital necessary to create a valuable product out of the idea. The marriage of intellectual property and its developmental partner is the basis of Bayh-Dole's success.

2. Bayh-Dole creates the incentive for universities and researchers to ignore their search for knowledge and to be motivated like "crack addicts" driven by "small minded tech transfer offices" addicted to patent royalties. Response: Wow! Such conclusions can only come from those who have no familiarity with the dedication of our universities and their faculties to spread knowledge and have no understanding whatsoever of what motivates those who devote their lives to science and the educational process.

I well remember the testimony of Dr. Leland Clark, of the Children's Hospital Research Foundation. Dr. Clark's obsession was finding practical solutions to improve the lives of the children and adults facing cancer and serious burns. Here's what he told the Senate Judiciary Committee in strongly endorsing the Bayh-Dole bill and describing the mindset of researchers and the role of the few who also became inventors:

"The point is, as part of the mental process which leads to an invention, the inventor often envisions possibilities for application which are not immediately evident to others. The inventor's personal persistence and confidence is often the deciding factor which carries the idea forward and prevents the invention from being set aside or ignored."

3. Researchers/inventors should not share in the royalties granted universities for licensing the product of their research. Response: Bayh-Dole specifically requires a university to reach an agreement with its researcher/inventor so that he or she would continue to assist in the development of the idea until it reached the public. Prior to Bayh-Dole, the researcher/inventor would patent the invention, write a paper for publication in a reputable publication, and return to his laboratory for more research. The idea gathered dust; the public suffered. In addition, Bayh-Dole says to the inventor, "Write your paper, receive recognition among your peers, follow your idea until it is developed so that individuals and society benefit from it."

4. Industry alliances are tainting university research away from basic toward applied research. Response: A National Science Foundation study found no evidence of such a shift.

5. Bayh-Dole has adversely impacted the publication of scientific papers by academia. Response: The U.S. remains by far the leading source of science and engineering publications.

6. Here's the real zinger. There should be no exclusive licenses. They should be made available to all. This criticism is heard repeatedly. Response: Without protection, business and industry will not expend (risk) the large amount of capital necessary to get an idea to the marketplace. It was this same philosophy that resulted in the 28,000 patents drawing dust that Joe

Allen discovered in the PTO in 1978. This sounds so simple, so equitable. The taxpayer pays for the research and makes the results available to everyone. Yet to follow this course of action would turn back the clock of history. It reminds me of the admonition given to us long ago by noted philosopher and historian George Santayana who said, "Those who fail to learn from history are doomed to repeat it." Will we never learn? Or, as another noted philosopher Yogi Berra observed, will we have "déjà vu all over again?"

There are other criticisms of Bay-Dole, equally lacking in merit. They constitute a relatively small clique who, by repeatedly using one another as an authority, appear to represent a large segment of learned opinion in the U.S. This is not the case.

Enough attention to the criticism, after 25 years a successful law should have produced tangible results. Here's what *The Economist* had to say in 2002:



"Possibly the most inspired piece of legislation to be enacted in America over the past half century was the Bayh-Dole Act of 1980...More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance...

"The Bayh-Dole Act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers got a piece of the action.

"Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies on their own."

Let's review some statistics from the most recent Association of University Technology Manager's survey. Under the provisions of Bayh-Dole:

- 137 non-profit institutions introduced 567 new commercial products through their licensing agreements in FY 2004.
- 185 institutions have introduced 3,114 new products through licensing since 1998.
- 16,871 invention disclosures were reported, up 8.8% over the previous year (about 250 university inventions were disclosed in 1980, the year prior to Bayh-Dole).
- In 2004, 462 new companies were formed, based on academic research (an increase of 23.5% over the previous year).
- 67.8% of university licenses went to small businesses.

But these are just statistics. Consider the new products benefiting not just the United States, but the world: Cisplatin Citracal, a new treatment for Crohn's disease; recombinant DNA technologies; the nicotine patch; better monitoring of diabetes patients; techniques to reduce infant respiratory deaths; 3-dimensional surgery technologies; new crops; and even the Google search engine all sprang from university research. There are many others.

So here is my challenge to the members of LES who know much more than I will ever know about this very sophisticated area. Where are we? The hard fact is that we are in danger of losing the larger philosophical war unless we explain to policy-makers and the general public why protecting intellectual property is important not only economically, but also ethically. Also, we need to understand that hidden in some of the attacks on Bayh-Dole is a veiled assault on our country's patent system.

Our patent system and Bayh-Dole provide incentives and rewards for successful risk-taking. We should be proud of this and bold in its defense. We shirk this responsibility at great risk.

Look at the hard fact: We have allowed our critics to dominate the public forum for too long, thinking that the fallacies of their arguments are transparent. This is a dangerous assumption and one that if left unchecked will undo us. This can happen literally overnight. Legislation in the form of "patent reform" is pending in Congress at this very moment. If it should pass, it would do irreparable harm to our economic growth and our ability to provide sophisticated solutions to the problems which face our society.

We hope that someone else will step into the breach since most normal people do not enjoy conflict, particularly when their integrity and motives may well be attacked. But, to my friends of LES, unless we pick up the gauntlet, no one else will. We cannot remain complacent. This is true of us as individuals and true of the United States of America. We must remember how Edward Gibbons concluded his great volume, *The Decline and Fall of the Roman Empire:* "All that is human must retrograde if it does not advance. Nations, like individuals, are either moving forward in life or moving backward. We are never standing still. The ethical creation of wealth is the real challenge facing the world today."

Previously I have tried to convey the impact that a few dedicated citizens can have on our country's legislative process. If Ralph Davis, Howard Bremer, Norm Latker, and Joe Allen can harness the effort which provided us with Bayh-Dole, certainly those of us who are faced with basically the same challenge a generation later should be willing to stand up and be counted today!

Let me repeat, if we don't do it, who will? ■

## SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| | Inventor | University | Invention | Licensee | Approximate Investment |
|---|---|---|---|---|---|
| 1. | Walser | Johns Hopkins U. | Keto-Acid analogs of Amino Acids for treatment of uremia | Pfrimmer of Germany and Syntex of U.S.A | Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe. |
| 2. | Wiktor | Wistar Institute | Rabies Vaccine | Wyeth Laboratories | On the market - millions |
| 3. | Kamen et al | Case Western Res. | Methotrexate Assay during Cancer Chemotherapy | Diamond Shamrock Corp. | Being test-marketed. Production scheduled for late 1977. Millions. |
| 4. | Lillehei/Kaster | U. of Minnesota | Pivoting Disc Heart Valve | Medical, Inc. | Being sold in world-wide market since 1971. Millions. |
| 5. | Blackshear et al | U. of Minnesota | Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.) | Metal Bellows Co. | Undergoing clinical trials. $750,000. |
| 6. | DeLuca | U. of Wisconsin | 25-Hydroxycholecalciferol for treatment of Osteo-dystrophy with liver dysfunction | Rousel-Uclaf (Hoechst) and<br>Upjohn | Have applied for equivalent of NDA in France. Approximately $5 million.<br>About to apply for an NDA and an NAOA. Will spend about $10 million. |
| 7. | DeLuca | U. of Wisconsin | 1-Alpha Hydroxycholecalciferol for treatment of Osteo-dystrophy with Kidney Dysfunction | Leo Pharma-ceuticals | Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. $5,000,000. |

## SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| | Inventor | University | Invention | Licensee | Approximate Investment |
|---|---|---|---|---|---|
| 8. | DeLuca et al | U. of Wisconsin | 1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy | Hoffman-LaRoche Inc. | About to apply for NDA. Will spend about $10 million. |
| 9. | Fox | Columbia U. | Silver Sulfadiazine used in Treatment of Burns | Marion Labs., Kansas City, Mo. | Now on market - Approx. $5,000,000 |
| 10. | Heidelberger | U. of Wisconsin | Use of $F_3$TDR for Herpes Infections of the Eye | Burroughs Wellcome Co., Research Triangle Park, N.C. | Approx. $5,000,000 NDA expected by end of 1977. |
| 11. | Fischell | Johns Hopkins U. | Rechargeable Cardiac Pacemaker | Pacesetter Systems Sylmar, California. | On market since Feb. 1975 - Approx. $720,000 |
| 12. | Holland | Tulane U. | Method of Reducing Intraocular Pressure in the Human Eyes (Glaucoma Treatment) | Cooper Labs., Bedford Hills, N.Y. | $2,000,000 - Development leading to NDA is in process and on schedule |
| 13. | Pressman | U. of Miami | Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.) | Hoffman-LaRoche, Nutley, N.J. | $500,000 to $1,000,000 Clinical evaluations still in progress |
| 14. | Higley | Natl. Institute of Scientific Research | Polycarbonate Dialysis Membranes (kidney dialysis) | C. R. Bard Inc., Murray Hill, N.J. | Over $1,000,000. Market introduction expected imminently. |
| 15. | Talbot/Harrison | Johns Hopkins U. | Ballistocardiograph Apparatus | Royal Medical Corp. Huntsville, Ala. | Approx. $330,000. Now on market. |

## SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| | Inventor | University | Invention | Licensee | Approximate Investment |
|---|---|---|---|---|---|
| 16. | Plotkin | Wistar Institute | Rubella Vaccine | 1) Wellcome Foundation<br>2) L'Institut Merieux<br>3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.) | Approx. millions - Now on market. |
| 17. | Schaffner/Mechlinski | Rutgers U. | Derivatives of Polyene Macrolide Antibiotics | E.R. Squibb of U. S. A. and Dumex of Denmark | Millions - Clinical trials progressing favorably |
| 18. | Zweig | Syracuse U. | Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium | New Brunswick Scientific Co., Inc., of New Jersy | Millions - On the market since 1973 |
| 19. | Lovelock | Yale U. | Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors | Varian Associates, Palo Alto, Calif. | On the market |
| 20. | Fried | U. of Chicago | Prostoglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc. | Richardson-Merrell, New York, N.Y. | Several millions - In process of development and testing for marketing here and abroad |
| 21. | Leininger/Grotta et al | Battelle Memorial Institute | Preparation of Non-thrombogenic Surfaces and Materials | C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California. | $107,754 - Some products being marketed and others being tested. |

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| Inventor | University | Invention | Licensee | Approximate Investment |
|---|---|---|---|---|
| 22. Merrifield | Rockefeller U. | Apparatus for the Automated Synthesis of Peptides | Beckman Instruments, Fullerton, California | Being marketed since 1973. |
| 23. Smith/Kozoman | Duke U. | Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid | Bellco Glass, Inc. Vineland, New Jersey | $25,000 - Being marketed since June 9, 1976 |
| 24. Zweng | Stanford U. | Laser Photocoagulator | Coherent Radiation, Palo Alto, Cal. | Approximately $500,000 Standard tool of ophtholmologists |
| 25. Sweet et al | Stanford U. | Cell Sorter | Becton-Dickinson, Rutherford, New Jersey | Approx. $200,000. Import research tool |
| 26. Boyd/Macovski | Stanford U. | Computerized Axial Tomography | S.A.I. Cupertino, Cal. | Approx. $300,000. Will be marketed soon. |
| 27. Saxena | Cornell U. | Method for Testing for Pregnancy | Carter-Wallace | Approx. 1/2 million On market |
| 28. Calnek/Hitchner | Cornell U. | Cell-free virus Preparation | Merck | |
| 29. Carlson | Iowa State | Respiratory Augmentor with Electronic Monitor and Control | Bourns, Inc. | On market since 1966; sales now in millions |
| 30. Leake/Rappoport | Harbor General Hospital | Bone Induction in an Alloplastic Tray | Am. Hospital Supply | Data not available |

## SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| | Inventor | University | Invention | Licensee | State of Development |
|---|---|---|---|---|---|
| 31. | Bradford/ Williams | U. of Georgia | Protein Assay Reagent and Method | Bio-Rad Labs, Inc; Quantimetrix Corp. | On the market since April 1977 |
| 32. | Tenckhoff | U. of Washington | Catheter Insertion Trocar | Sweden Freezer Mfg. Co; Cobe Labs; Physio-Control Corp; | On market |
| 33. | Leonard et al | U. of Illinois | Fluorescent Derivatives of Cytosine-Containing Compounds | PL Biochemicals | On market |
| 34. | Secrist et al | U. of Illinois | Fluorescent Derivatives of Adenine-Containing Compounds | PL Biochemicals | On market |
| 35. | Asgar | U. of Michigan | Partial Denture Alloy | | On market |
| 36. | Carlson/Ward | U. of Washington | Coherent Biological Cell Analyzer | 3M Company | Marketing development in progress. |
| 37. | Charlson/ Alhquist | U. of Washington | Integrating Nephelometer and Photon-Counting Integrating Nephelometer | Battelle Development | On market |
| 38. | Thomas | U. of Washington | Artery-Vein Shunt Applique | Battelle Development Corp. | Being marketed |

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

| | Inventor | University | Invention | Licensee | State of Development |
|---|---|---|---|---|---|
| 39. | Holcomb | Yale University | Method and Apparatus for Stimulation of Body Tissue | Avery Labs, Inc. | On the market since 1973 |
| 40. | Dugan | Temple University | Novel Compositions for Radiotracer Localization of Deep Vein Thrombi | Rand Research & Development Corp. | Licensed in 1977. |
| 41. | Roelofs | Cornell University | Codling Moth Pheromone | Zoecon Corp. | On market since 1972. |
| 42. | Whitby | Univ. of Minnesota | Particle Counter | Name not available | On market since 1969 |
| 43. | Backaner | Univ. of Minnesota | Method for Suppressing Ventricular Fibrillation | Burroughs Wellcome | About to be marketed |
| 44. | Whitby | Univ. of Minnesota | Aerosol Sampler | Not available | On market since 1969 |
| 45. | Bradley | Univ. of Minnesota | Apparatus to Stimulate the Bladder | Two licenses, names not available | On market since 1972 |
| 46. | Blackshear | Univ. of Minnesota | Implantable Infusion Pump | Metal Bellows Company | About to be marketed |
| 47. | Lillehei | Univ. of Minnesota | Pivoting Disc Heart Valve | Name not available | On market world-wide since 1971 |
| 48. | Butler | Purdue Research Fdn. | Hydrophobic Noncovalent Binding of Proteins to Support Materials | Regis Chemical | On market since April 1977 |

| Inventor | University | Invention | Licensee | State of Development |
|---|---|---|---|---|
| 49. Rosenberg | Michigan State Univ. | Platinum Compounds as Anti-Tumor Agents | Possibly Adria, Bristol or Miles Labs. | On market in late 1977 |
| 50. Coller | Institute for Cancer Research | Process of Viral Diagnosis and Reagent (Radioimmuno-assay) | Abbot Labs. | Licensed in 1977 (Canada) On market in U.S.A. |
| 51. Kosikowski | Cornell University | Antibiotic Test Kit | Bacto Strip | On market |
| 52. Kosikowski | Cornell University | Process for Milk Sterilization | De Laval Alpha Laval | On market |
| 53. McLafferty | Cornell University | Pregnancy Test | Carter-Wallace | On market |
| 54. Kattwinkel et al | Case Western Reserve | Device for Administering Pressure via Nasal Route | Sherwood Medical | On market since 1975 |

| | Inventor | University | Invention | Licensee | State of Development |
|---|---|---|---|---|---|
| 2. | Simmons, F. B. | Stanford Univ. | Crib-o-gram | Corp-Telesensory Systems, Inc. | Commercial production fall 1978 |
| 3. | Meindl/Hottinger | Stanford Univ. | Arterial Flow Meter | Ultrasonic Diagnostics, Inc. | Being developed commercially |
| 4. | Butler/Kelly | Purdue University | Phosphonate Monoesters as Specific Convenient Substrates..... | Regis Laboratories | Available for research purposes |
| 5. | Javid et al | Rockefeller Univ. | Radioimmune Assay for Hemoglobin $A_{1_c}$ | Pfizer, Inc. | In commercial development |

The Office of NIH History
Dewitt Stetten Jr., Museum

45 Center Drive, MSC 6330
Building 45 Room 3AN38
Bethesda, MD 20892-6330
Tel: 301.496.6610 | Fax: 301.402.1434
history@nih.gov | www.history.nih.gov

RECEIVED
WITH THANKS
OCT 27 2008
BROWDY AND NEIMARK, P.L.L.C.
WASHINGTON DC 20001-5303

October 22, 2008

Norman J. Latker
Browdy and Neimark, P.L.L.C.
Suite 300, 624 Ninth Street, N.W.
Washington, District of Columbia 20001-5303

Dear Mr. Norman J. Latker,

I am writing to see whether you are willing to help my historical research. I got a PhD in history from Princeton University and am currently a Stetten fellow at the NIH History Office.

My dissertation research examines the history of recombinant DNA research and technology, focusing on its commercialization in the 1970s at Stanford University. One of my dissertation chapters deals with the role of university technology transfer managers (such as Neils Reimers) and government officials (Norman Latker) in the transfer of the ownership of recombinant DNA technology to Stanford and University of California.

I realize you played a significant role in the catalytic events for the emergence of the biotechnology industry. I am interested in your role as a patent council at the NIH in instituting IPAs. Throughout your career at the NIH, you articulated a distinctive view of the ownership of biomedical inventions. As early as the late 1960s, you argued that private ownership could actually liberate biomedical discoveries for public benefit. I would like to know how and in what circumstances you developed this influential view and how you promoted this view, which eventually led to the Bayh-Dole Act of 1980.

Recognizing you are a renowned lawyer with many demands on time, it would be a great help for me if you are willing to meet me. I attach my CV and dissertation abstract for your information. I live in Bethesda and can come by your office when you are available. Except Tuesdays and Fridays, I am mostly available. I look forward to hearing from you. My contact information is below:

Sincerely,
Doogab Yi

*Doogab Yi, Ph.D.*
*Office of NIH History*
*Bldg 45, Rm 3AN.44J, MSC 6330*
*Bethesda , MD 20892-6330*
*Phone: 301-443-4788*
*Email: yid@mail.nih.gov*

# Doogab Yi
## *Curriculum Vitae*

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**Current Position**

*DeWitt Stetten, Jr., Fellow in the History of Biomedical Sciences and Technology*, National Institutes of Health, 2008 - Current

**Education**

*Ph.D. in History*, Princeton University, 2008
*Visiting Scholar*, University of Pennsylvania, 2007–2008
*Gore Fellow*, Center for Contemporary History and Policy, Chemical Heritage Foundation, 2007–2008
*Visiting Scholar*, Stanford University, 2005–2006

*M.A. in History*, Princeton University, 2002–2004
General Examination Fields:
Major: History of Biology (Prof. Angela N.H. Creager)
Minor: History of Technology (Prof. Michael S. Mahoney)
Minor: Modern US History (Prof. Kevin Kruse)

*M.S. in History and Philosophy of Science*, Program in History and Philosophy of Science, Seoul National University, 1998–2000

*B.S. in Environmental Sciences*, College of Natural Sciences, Seoul National University, 1998

**Refereed Publications**

"The Scientific Commons in the Marketplace: The Industrialization of Biomedical Materials at the New England Enzyme Center, 1963-1980," *History and Technology* (*Forthcoming* in 2009)

"Cancer, Viruses, and Mass Migration: Paul Berg's Venture into Eukaryotic Biology and the Advent of Recombinant DNA Research and Technology, 1967-1974," *Journal of the History of Biology* (*In press* for Volume 41 (2008): http://dx.doi.org/10.1007/s10739-008-9149-9)

"The Coming of Reversibility: The Discovery of DNA Repair between the Atomic Age and the Information Age," *Historical Studies in the Physical and Biological Sciences*, 27 (2007), pps. 35-72.

**Fellowships and Awards**

*Robert W. Gore Fellowship*, Center for Contemporary History and Policy, Chemical Heritage Foundation, 2007 –2008

*(Alternate List),* American Council for Learned Society, Andrew W. Mellon Foundation Dissertation Completion Fellowships, 2007.

*Maurice Biot Grants-in-Aid*, California Institute of Technology, December 2006
*National Science Foundation Dissertation Improvement Grant*, Science and Technology Studies Program, National Science Foundation, 2005-2007
*Rollins Prize in History*, Princeton University, 2005-2006
*Graduate Alumni Research Travel Grant*, Princeton University, 2005
*Grants-in-Aid*, Center for the History of Physics, American Institute of Physics, 2004
*Predissertation Research Award*, History Department, Princeton University, 2004
*Davis Merit Fellowship*, Davis Center for Historical Studies, Princeton University, 2003-2005, 2006-2007
*Graduate Fellowship*, Princeton University, 2002 – 2008
*Research and Teaching Assistantship*, Seoul National University (1999-2000)

**Appointments & Teaching**

*DeWitt Stetten, Jr., Fellow in the History of Biomedical Sciences and Technology*, National Institutes of Health, 2008 - Current
*Assistant Editor*, *Journal of the Korean History of Science Society* (2001)
*Lecturer*, Division of Liberal Arts, College of Humanities and Natural Sciences, University of Seoul, South Korea, 200 –2002 (history of science and technology, science and society)
*Lecturer*, Department of Chemistry, College of Liberal Arts and Sciences, KyungHee University, South Korea, 2000–2002 (history of science, history of biology, and environmental history)
*Lecturer*, Department of History, College of Humanities, Hankuk University of Foreign Studies, South Korea, 2001 (history of science and technology)

**Conference Presentations**

"Toward the Regulatory Vision of Development: Models for Animal Chromosomes and David Hogness's Construction of Drosophila Recombinant DNA Libraries, 1967-1987." History of Science Society Meeting, Arlington, VA, November 2007. *Session: The Rise of Modern Biological Subspecialties*
"From Laboratory to Factory and Vice Versa: Gift and Commodity in Biomedical Materials Exchange and Production at the New England Enzyme Center, 1962-1980." Society for the History of Technology Meeting, Washington, DC, October 2007. *Session: Marketing Medicine*, Commentator: Margaret Weitekamp
"DNA and the Communal Form of Experimental Life: the Early History of the Biochemistry Department at Stanford University, 1959-1980." Program Seminar for History of Science, Princeton University, April 2006.
"Instituting Biomedical Research at Stanford: the Establishment of the Biochemistry Department at the Stanford Medical School, 1953-1964." Joint Atlantic Seminar for the History of Biology, Johns Hopkins University, March 2006. *Session: Business as Unusual*
"The Coming of Reversibility: the Discovery of DNA Repair Amidst Nuclear Fear." History of Science Society Meeting, Minneapolis, MN, November

2005. *Session: Human and Animal Bodies in the Age of Nuclear Fear*, Commentator: Jacob Hamblin

"The Development of Recombinant DNA Research at the Department of Biochemistry at Stanford University, 1968-1974." International Society for the History, Philosophy, and Social Studies of Biology Meeting, July 13-17, 2005. Organizer, *Session: Trailblazing the History of Molecular Biology in the 1960s and 1970s*, Commentator: Nathaniel C. Comfort

"The Order of Nature and the Computer: Evolutionary Taxonomy Versus Numerical Taxonomy, 1957-1970," 44th Annual Meeting of the National Historical Association of Korea, May 2001.

**Other Experience**

*Research Assistant*, "A Study on the Development and Current Status of the Research System in Universities in Advanced Countries." Science and Technology Policy Institute (July 2001- July 2002), South Korea

*Research Assistant*, "A Basic Plan for the Promoting of the Infra-Structure of Science and Technology in Seoul." Ministry of Science & Technology and Seoul Metropolitan Government (July 2000-July 2001), South Korea

*Research Assistant*, "Long-Term Forecasts on Demand and Supply of R&D Personnel: 2000-2010." Korea Science and Engineering Foundation (August 2000-September 2000), South Korea

**Refereed Publications in Korean**

"The Boundaries of Humanity: Technological Determinism in a Historical Perspective." (with Chihyung Jeon) *Journal of the Korean History of Science Society* 23:2 (2001): 157-179.

# THE RECOMBINANT UNIVERSITY:

## GENETIC ENGINEERING AND THE EMERGENCE OF BIOTECHNOLOGY AT STANFORD, 1959-1980

**Doogab Yi**

A DISSERTATION

PRESENTED TO THE FACULTY

OF PRINCETON UNIVERSITY

IN CANDIDACY FOR THE DEGREE

OF DOCTOR OF PHILOSOPHY

RECOMMENDED FOR ACCEPTANCE

BY THE HISTORY OF SCIENCE PROGRAM

IN THE DEPARTMENT OF HISTORY

September 2008

# Abstract

This dissertation investigates the development of recombinant DNA research and technology from its academic origins in the 1970s to its commercialization in the 1980s at Stanford University. More specifically, this dissertation offers an alternative to standard histories of the development of recombinant DNA technology by revising the canonized history of the origins of genetic engineering that emerged during the patenting of Stanley Cohen and Herbert Boyer's recombinant DNA cloning procedures. I do so by approaching its history not from the usual perspective of its legal inventors, but from the perspective of Stanford biochemists, whose central role in its scientific development and whose reservations toward its commercialization have not been well acknowledged. Through this shift of investigative focus to Stanford biochemists, my dissertation offers a detailed, technical history of the development of recombinant DNA research and technology within molecular biology, one that is grounded on an appreciation of the dynamics of laboratory experimentation.

The dissertation offers a technical analysis of the advent of recombinant DNA technology and follows the story of the commercialization of academic research through its shifting institutional, political, and cultural contexts. First of all, I situate Stanford biochemists' development of recombinant DNA technology in the context of a mass migration of biomedical researchers into the biology of higher organisms, which concurred with increasing calls for practical relevance in biomedical research. It was when molecular biology was experiencing this political and epistemological context that recombinant DNA technology emerged as a new research technology for eukaryotic biology. This dissertation then examines a series of unexpected experimental hybridizations through a research network formed around Stanford

biochemists: first, the adoption of recombinant DNA as a research technology for cloning in plasmid and bacteria research; and second, the application of recombinant DNA technology for the analysis of the genome of *Drosophila*, which in turn opened an epistemological space for a molecular approach to the study of developmental biology.

This dissertation in turn analyzes how recombinant DNA technology evolved from a research technology to a cultural-technological entity – biotechnology – in relation to changes in research patronage, market forces, and legal developments during the 1970s and 1980s. In particular, I examine the contentious transition from academic biomedicine to commercial biotechnology from the perspective of Stanford administrators and scientists. Taking account of the changing political and economic landscape for biomedical research during the 1970s, Stanford research administrators allied with some governmental officials to promote the private ownership of recombinant DNA technology as a viable means of technology transfer. I analyze those threads of policy-informed ideas that came together to affirm private ownership of scientific knowledge as germane to public interests. The dissertation concludes with a discussion of how Stanford biochemists tried to grapple with the increasing commercialization of biomedical research in the late 1970s and early 1980s. My investigation of Stanford biochemists' cautious engagements with the biotech industry illuminates the emergence of a "new moral economy of science" as well as a new form of "biomedical enterprise" deeply networked with the financial regimes of late twentieth century capitalism.

Marty Gleason 245-7627
HEW
a must !!

To: Senator
From: Joe
Re: Norman Latker firing at HEW
Oct 10, 1979

As you remember from the hearing on the patent bill there is a great deal of concern about the HEW actions that were taken against their patent counsel Norman Latker.

At the time of the first action you talked directly to Dick Warden about your concerns about the Latker case and were assured that none of the charges were related to your patent bill. Latker was ordered to be reinstated by a Civil Service review board because HEW had not followed the proper procedures. This seemed to be the end of the matter until Norman was called in approximately one month ago and presented with four charges, three of which are classified as use of appropriated funds to attempt to influence Members of Congress.

One of these charges is that Latker mailed out 8 copies of your press release to university officials who had requested it when you put in your patent bill.

The second was that he sent Mr. Howard Bremer of the University of Wisconsin a copy of a list of staff for each Senator's office who had responsibility for patent matters.

The third was that he had taken to a meeting of the National Association of College and University Business Officers some of your statements regarding S. 414.

S. 414 is based on the IPA program which Latker implemented at HEW after the 1968 GAO study found that not one drug could be found that had reached the market when HEW retained patent rights. The IPA program is still in effect at HEW and was made available by the General Services

Additionally when we learned that HEW was planning on renewing its attempts to fire Latker, Tom called and asked that you be kept informed of any actions before they were taken. HEW agreed to this request and then proceeded to initiate their actions without any word to us. The HEW liason's office has not returned numerous phone calls that Tom and I have made in an attempt to find out what the situation was.

Patricia Harris also turned down your request that Latker be allowed to work on S. 414 when the bill is considered by the Committee. The Small Business Administration has also asked HEW that they be allowed to use Latker's talents because of his knowledge of Government patent policy and they were also turned down.

The present Acting Assistant Secretary for Legislation is Martin Gleason whose number is 245-7627.

The American Patent Law Association has also expressed its concern over the actions taken against Latker last year and they are preparing another letter to protest the most recent actions.

EDWARD M. KENNEDY, MASS., CHAIRMAN
BIRCH BAYH, IND.
ROBERT C. BYRD, W. VA.
JOSEPH R. BIDEN, JR., DEL.
JOHN C. CULVER, IOWA
HOWARD M. METZENBAUM, OHIO
DENNIS DECONCINI, ARIZ.
PATRICK J. LEAHY, VT.
MAX BAUCUS, MONT.
HOWELL HEFLIN, ALA.
STROM THURMOND, S.C.
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PAUL LAXALT, NEV.
ORRIN G. HATCH, UTAH
ROBERT DOLE, KANS.
THAD COCHRAN, MISS.
ALAN K. SIMPSON, WYO.
DAVID BOIES
CHIEF COUNSEL AND STAFF DIRECTOR

SUBCOMMITTEE:
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ALAN K. SIMPSON, WYO
NELS ACKERSON, CHIEF COUNSEL AND EXECUTIVE DIRECTOR
MARY K. JOLLY, STAFF DIRECTOR
KEVIN O. FALEY, GENERAL COUNSEL

# United States Senate

COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON THE CONSTITUTION
WASHINGTON, D.C. 20510

June 4, 1979

Mr. Daniel DeSimone
Acting Director
Office of Technology Assessment
600 Pennsylvania Avenue
Washington, D.C. 20510

Dear Mr. DeSimone:

There has been a great deal of concern in the Congress, which we share, that the United States is rapidly losing its competitive edge in innovation and productivity, along with the related problem that many promising inventions that are made each year under Government-supported research and development never achieve their potential in the marketplace because of ineffective Government policies.

We believe in this regard that the Office of Technology Assessment can make an important contribution toward solving this problem. We also understand that your office has received a resume from Mr. Norman Latker, whom we feel has invaluable expertise in the field of Government research combined with an excellent understanding of the innovation process.

Mr. Latker has worked with us on S. 414, the University and Small Business Patent Procedures Act, which is a first step in addressing the overall problem of getting inventions out into the marketplace where they can benefit the public. We strongly recommend that you give Mr. Latker a very serious consideration for employment at the OTA because we believe that he will prove to be a great asset for your office in an area of tremendous importance not only to the Congress, but to the continued prosperity of our country.

Sincerely,

Birch Bayh

Bob Dole

Charles McC. Mathias

COMMENTS OF THE WISCONSIN ALUMNI RESEARCH FOUNDATION ("WARF")
on Committee Draft Bill on Patent Law Reform

WARF supports a strong, high-quality, predictable and consistent patent system and an effective United States Patent and Trademark Office ("USPTO"). WARF therefore supports a post-grant opposition procedure and various administrative improvements in the USPTO, provided that these reforms are drafted properly and do not disadvantage inventors and universities. WARF opposes measures to weaken the patent law and thereby choke innovation, such as the proposed reforms to injunctive relief, monetary damage relief, the extension of prior user rights and the removal of limitations regarding prior commercial use. WARF also opposes the adoption of a first-to-file system which does not provide any substantive protection against misuse or protection against misappropriation of the rights of the true inventor. Finally, WARF opposes substantive reform to the CREATE Act and other substantive reforms not germane to the Committee Print, including but not limited to amendments to the Bayh-Dole Act, sovereign immunity reforms that jeopardize technology transfer and university licensing to the private sector, and codification of a research exception in the Patent Act.

WARF holds a deep concern that the proposed legislation set forth in Committee Print will substantially weaken the principles of patent law established over the past 200+ years. The fundamental principle underlying patent law has been the grant of exclusivity to the patent holder in return for a full public disclosure of the invention and the surrender of the right to obtain commercial benefit from the invention prior to seeking patent protection. The proposed reforms would undermine this basic principle as the changes to the patent laws would allow for the commercial exploitation of inventions for an undeterminant amount of time prior to seeking patent protection and, once patent protection is sought, allow for the withholding of the best mode for practicing that invention. It is believed that such a fundamental change to our patent system is likely to stifle innovation as it will promote an environment of nondisclosure, thereby weakening the very principles under which U.S. patent law has been established.

WARF supports and agrees with the positions set forth in the University of California Comments on House Draft Patent Reform Bill dated April 21, 2005, and provides the following comments as a supplement to those put forward by the University of California. WARF looks forward to working with the Subcommittee and the full Committee to achieve improvements to the patent system.

1. FIRST INVENTOR TO FILE (Section 3 of the Committee Print)
**WARF opposes the first inventor to file system as presently proposed.** WARF agrees that moving to a first inventor to file system will provide a significant disadvantage to individual inventors, small businesses and research colleges and universities, and create an environment that is ripe for misuse and the misappropriation of inventions conceived and reduced to practice by others. University researchers are encouraged to publish their discoveries and achievements, often times leading to post-publication filings. WARF is concerned that in the absence of any legitimate process for determining or challenging inventorship, or any penalties for the wrongful claim of inventorship, an environment would be created that allows for the misappropriation of inventions by an individual, corporation or other entity that happens to review a publication disclosing all or part of an invention.

2. PRIOR ART; REPEAL OF THE CREATE ACT (Bill Section 3 of the Committee Print)
**WARF opposes the repeal of the CREATE Act and the removal of the "on sale" bar to patentability.** WARF agrees with the suggestions made by the University of

California to maintain the elements of the CREATE Act. The elimination of secret prior art is presumed to have been addressed by the suggested amendments to Section 102(c)(1) and (2), however, new proposed Section 102(c) is inadequate to achieve that result in that it is incomplete in stating to whom the subject matter is "reasonably and effectively accessible." With respect to the "on sale" bar, Section 102(a)(1)(A) as proposed in the Committee Print should be modified to include the "on sale" bar as included in original Section 102(b).

3. PRIOR USER RIGHTS (Section 9 of the Committee Print)
**WARF opposes the expansion of prior user rights.** The proposed broad scope of "prior user" rights in principle favors trade secret practices in contrast to the disclosure inducement theory advanced by the Constitutional basis for the patent system. Moreover, the extension of the defense to "made substantial preparation for commercial use" is an invitation to mischief, greater disputes and increased costs, duration and complexity of patent infringement litigation. Section 9(b) as proposed by the Committee Print will not improve patent quality or promote innovation, but will more likely stifle innovation and increase the costs of litigation.

4. CONTINUING APPLICATIONS (Bill Section 8 of the Committee Print)
**WARF opposes the amendment to Section 123 limiting the breadth of claims in continuing applications.** Adoption would further increase the burden placed on the USPTO as the amendment would require the applicant to submit substantially more claims for examination, thus increasing the cost and duration of the examination and the likelihood of multiple restriction requirements. The amendment would also increase the expense associated with filing patent applications as the applicant would be required to submit substantially more claims and provide more speculation with respect to claim construction and potential uses for the claimed invention. The amendment as written is also inconsistent with the rights afforded to divisional applications under existing Section 121 as it is unclear as to whether proposed Section 123(a)(2) would limit an applicant's ability to obtain patent protection for those inventions claimed in later filed divisional applications. As a result, the individual inventor, small business and research college or university may be required to filing multiple applications at the same time in order to cover those inventions that may potentially be subject to a restriction requirement.

5. INJUNCTIONS (Section 7 of the Committee Print).
**WARF opposes the elimination of the presumption of irreparable harm to the patentee with respect to permanent injunctions.** The fundamental right under a patent is the right to exclude others from practicing the patented invention. The amendment proposed by Section 7 of the Committee Print takes away this fundamental right and removes any risk placed on an infringer through the threat of injunctive relief in favor of what amounts to a compulsory or forced licensing through the payment of damages. The proposed amendment, coupled with the proposed elimination of treble damages for willful infringement, would substantially impede the ability of research colleges and universities to effectively license their technologies. First, the amendments would remove the primary motivation for licensing and provide, in return, a stronger motivation for larger industries to not take a license and to depend upon the individual, small business or research college or university to bring an infringement action in order for the court to grant a compulsory license. For smaller research colleges and universities, bringing such an infringement action may not be an option. Second, the fact that any court could grant a license to an infringer may deter the decision to license by a potential licensee due to the lack of security with respect to the exclusivity of their license. Such investment risk

is an extremely important factor in the biotechnology and health-care fields where development time and costs tend to be extraordinarily high.

6. POST-GRANT OPPOSITIONS (Section 9 of Committee Print).
**A limited post-grant opposition procedure is supported by WARF with appropriate curative amendments to provide reasonable time limitations, a full disclosure of the real party in interest and a broader range of the estoppel effect of the opposition.** As presently drafted, coupled with the removal of the estoppel effect afforded to reexaminations, a patent holder could be subject to multiple attempts by a party to invalidate the patentabilty of the subject invention. Arguably, the patent holder could be forced to address the same issues regarding patentability during post-grant opposition, reexamination and then litigation, all at substantial time and expense. Certain limitations should be incorporated into the process in order to stem abuse and to avoid delays in the patent holders ability to enjoy the rights afforded by his patent.

7. RIGHT OF INVENTOR TO OBTAIN DAMAGES (Section 6 of Committee Print)
**WARF opposes the amendments (as drafted) to 35 U.S.C. Sections 284(d)(2) and 284(e).** Section 6 of the Committee Print amends 35 U.S.C. 284(d)(2) to limit the granting of increased damages. The criteria for relief, "that the defendant had an informed and good faith belief that a court would reasonably hold that the patent is invalid, not infringed or unenforceable" is a speculative and subjective basis, at best, for relief. The limitation in Section 284(e) to product components as opposed to sales prices of whole products is an inadequate measure. Often a sale of a whole product is dependent upon the presence of a patented improvement in a competitive environment. Courts are familiar with the concept of "whole market value" and "causation" as well as "convoyed sales."

8. DUTY OF CANDOR (Section 5 of Committee Print)
New section 137 sets forth limitations to the duty of candor as a defense in court and applies that duty to opposers in the post-grant opposition process. Presumably the goal is to limit the opportunity for financially-able and other parties to piecemeal present citations of allegedly material references in oppositions, reexaminations and/or litigation. This goal is highly desirable. The Subcommittee should seriously consider increasing the proposed penalties as deterrents to frivolous activities.

9. COMBINATIONS; COMPONENTS (Section 10 of Committee Print).
One of the great benefits of U.S. patent law is that it is technology neutral. Section 10 of the Committee Print -- which is drafted to benefit the computer software industry -- violates this cardinal principle. Section 10 focuses on the perceived needs of one segment of the users of the patent system. Per se it would seem to be applicable only to mechanical assemblies and would not address certain combinations in chemical, pharmaceutical and biotechnology arts. In this regard, it would seemingly harm these industries, in comparison to the software industry. If 35 U.S.C. Section 271(f) is no longer necessary, the Subcommittee should consider its repeal.

May 2, 2005

**SUPPLEMENTAL COMMENTS OF**
**WISCONSIN ALUMNI RESEARCH FOUNDATION ("WARF")**
**on Committee Draft Bill on Patent Law Reform**
**May 13, 2005**

WARF has been asked by staff to provide additional comments regarding various issues. , including suggestions about how to work towards consensus solutions. We take this opportunity to supplement our submission dated May 2, 2005, entitled *Comments of the Wisconsin Alumni Research Foundation on Committee Draft Bill on Patent Law Reform.* WARF supports patent reform that strengthens the patent system and enhances the capabilities of the U.S. Patent and Trademark Office, but opposes patent changes that disadvantage small businesses, individual inventors, universities and nonprofit research institutions. WARF therefore continues to support a post-grant opposition procedure and an enhanced duty of candor. WARF opposes, however, those measures that weaken the patent law and reduce the public dissemination of information, such as the proposed reforms to injunctive relief, monetary damage relief, the extension of prior user rights and the removal of limitations regarding prior commercial use. WARF also opposes the repeal of the CREATE Act (although WARF has been assured that it was unintentional and will be included in the bill to be introduced next week).

WARF has not been "in the room" for private-sector negotiations between and among the trade and bar associations and the congressional staff, and therefore is not privy to consensus solutions that may already have been developed. We are confident, however, that the bill to be introduced next week will contain a number of improvements. Nonetheless, because we are not aware of specific changes, WARF would like to reserve the right to modify the positions set forth herein upon receipt of any new language.

**Section 3: Right of the First Inventor to File**

**TOPIC: FIRST INVENTOR TO FILE**

WARF opposes a first inventor to file system without significant safeguards for universities and independent inventors as such a system is likely to have a negative impact on the manner in which research institutions and the academic community share discoveries with other researchers and the general public. U.S. universities foster an environment of openness in which researchers are encouraged to share their discoveries with others through peer-reviewed publication. Researchers are also encouraged to collaborate with industry in order to more effectively and efficiently develop and improve existing technologies. The proposed first inventor to file system is likely to substantially impact such an open environment.

**Recommendation:**
WARF recommends maintaining the first to invent system unless the first inventor to file system is tailored to promote public disclosure and to protect the true inventor from misappropriation by parties who have not made a significant intellectual contribution to the claimed invention. To accomplish this, WARF makes the following recommendations:

1. Modify proposed Section 115, Oath of Applicant, to require an oath on the part of the applicant that either he/she is an inventor or has been assigned the right to patent by the inventors. Section 115 as presently proposed does not require such an oath, but simply leaves it to the Director's discretion. In the least, the Director should be required to ensure that the claimed inventor declares under a threat of penalty that he is an inventor. This may be accomplished by modifying proposed Section 115, page 9, lines 18-20 to read as follows:

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"The Director shall require the applicant to make an oath setting forth particulars relating to the inventor and the invention."

2. Modify proposed Section 136(a), Duty of Candor, to specifically include the misrepresentation of inventorship, thus making it a violation of the duty of candor to falsely claim inventorship. This may be accomplished by modifying proposed Section 136(a), line 7, by inserting ", including any information regarding inventorship" after "to not materially misrepresent information".

3. Amend the definintion of "inventor" on page 2, lines 9-10, of the Committee Print, by replacing "person or persons" with "individual or individuals." Also, add the words "or discovered" after the word "invented".

4. Amend page 3, lines 10-11, by striking "A patent for a claimed invention may not be obtained if", and inserting "An inventor shall be entitled to a patent unless". This is a conforming change to render the language in section 102 consistent with that in section 101. It changes the language from a negative approach to a positive one, as the language has been since the 1952 Act.

5. Amend by on page 4, line 4-12, insert language necessitated by the recently-enacted CREATE Act.

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**Section 4: Right to Patent**

**TOPIC: BEST MODE**

The elimination of the "best mode" requirement elevates the status of trade secrets and compromises the fundemental agreement of the inventors with the government, which is to provide full disclosure in return for the patent grant. The removal would disadvantage universities as universities do not use trade secrets due to their open environment.

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**Recommendation:**
Amend by on page 10 strike lines 11-17

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**TOPIC: REMOVAL OF THE "ON SALE" BAR TO PATENTABILITY**

The fundamental principle underlying the United States patent system has been the grant of an exclusionary right to the patent holder in return for a full public disclosure of the invention and the surrender of the right to obtain commercial benefit from the invention prior to seeking patent protection. The new language proposed as Section 102(a)(1)(A) would undermine this basic principle because the "on sale" bar has been removed. Such removal would allow for the commercial exploitation of inventions for an indefinite amount of time prior to seeking patent protection. Such a fundamental change to our patent system is likely to stifle innovation as it will promote an environment of nondisclosure, thereby weakening the very principles under which U.S. patent law has been established.

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In particular, an inventor shall have no incentive to disclose his invention if he believes he can maintain it as a trade secret. If the inventor determines that his secret may be disclosed, the inventor could still file for patent protection under the presently proposed Section 102(a)(1)(A). Even if another inventor later independently attempts to patent the same invention, the earlier inventor could, under the presently

proposed Committee Print, either seek to invalidate such patent on the basis that the invention was known or claim prior user rights. The inventor, therefore, has no incentive to disclose his invention to the public to promote further development or innovation.

**Recommendation:**
WARF opposes the removal of the "on sale" bar to patentability, and suggests modifying presently proposed Section 102(a)(1)(A) to include the "on sale" bar as included in original Section 102(b). This may be accomplished by modifying proposed Section 102(a)(1)(A), page 3, line 12, by inserting "on sale," after "the invention claimed was".

## Section 7. Injunctions

**TOPIC: INTRODUCING GROUNDS FOR INJUNCTIONS**

The fundamental right under a patent is the right to exclude others from practicing the claimed invention. The amendment proposed by Section 7 of the Committee Print weakens this fundamental right and creates what amounts to compulsory or forced licensing through the payment of damages. The proposed amendment, coupled with the proposed elimination of treble damages for willful infringement, would substantially impede the ability of research colleges and universities to effectively license their technologies. These changes would encourage a corporation to simply infringe instead of negotiate up front for a license, because the result of an eventual infringement litigation would be, at worst, the involuntary grant of a license. The end result of such a system would be to encourage an increase in litigation. Such a change would also stifle investment in companies in the biotechnology and health-care fields because the law would, in effect, limit the ability of a company to exclusively develop a product.

**Recommendation:**
Therefore, Section 7 of the Committee Print should be deleted.

## Section 8. Continuation Applications

**TOPIC: LIMITATION ON THE ENLARGEMENT OF CLAIMS**

WARF opposes the amendment to Section 123 limiting the breadth of claims in continuing applications. Adoption would further increase the burden placed on the USPTO as the amendment would require the applicant to submit substantially more claims for examination, thus increasing the cost and duration of the examination and the likelihood of multiple restriction requirements. The amendment would also increase the expense associated with filing patent applications as the applicant would be required to submit substantially more claims and provide more speculation with respect to claim construction and potential uses for the claimed invention. The amendment as written is also inconsistent with the rights afforded to divisional applications under existing Section 121 as it is unclear as to whether proposed Section 123(a)(2) would limit an applicant's ability to obtain patent protection for those inventions claimed in later filed divisional applications. As a result, the individual inventor, small business and research college or university may be required to file multiple applications at the same time in order to cover those inventions that may potentially be subject to a restriction requirement.

**Recommendation:**
WARF recommends deleting Section 8 in the Committee Print.

TOPIC: PRIOR USER RIGHTS

WARF opposes the expansion of prior user rights to include a defense for making "substantial preparations for commercial use" of the claimed invention. Prior user rights is presently a defense to infringement limited solely to those instances where the invention has already been "commercially used" (i.e., as a trade secret) prior to the filing date of the patent application claiming the invention. The determination of whether or not the invention was in "commercial use" is reasonably clear and has been well developed by the case law.

The proposed changes to the prior user rights to include a defense for making "substantial preparations for commercial use" will introduce a substantial amount of ambiguity to the determination process. Under the proposed language, just making minor investments in market research could be construed to be substantial preparations. Because it is much harder to define what is "substantial" and what will constitute "preparation," the time and expense of infringement litigation could ultimately be dramatically increased and prolonged. Ultimately, the cost of such litigation will substantially affect the ability of the individual inventor, small business and research college or university to enforce its patent rights as companies could easily claim "substantial preparations for commercial use."

In addition, the proposed broad scope of prior user rights in principle favors trade secret practices in contrast to the disclosure inducement theory advanced by the Constitutional basis for the U.S. patent system. The expansion of prior user rights will not improve patent quality or promote innovation, but will more likely stifle innovation and increase the costs of litigation.

**Recommendation:**
WARF opposes the expansion of the prior user rights. However, if such expansion occurs, the term "substantial preparations for commercial use" should be clearly defined and limited to only those instances wherein the alleged infringer is only one step removed from actual commercial use. In other words, the alleged infringer is more than 90% of the way to final implementation prior to actual commercial use. This may be accomplished by including such a definition of "substantial preparations for commercial use" to the end of proposed Section 273(b)(1), page 35, line 4.

# Development Doesn't Require Big Government

**By William Easterly**

Financial meltdown will not cause the U.S. to abandon democratic capitalism, but the outcome is less clear for countries deciding whether capitalism is the best system. In many of these countries the choice is not between light and heavy financial regulation, but between relying on creative individuals or government planners to escape poverty.

Some countries are already taking the wrong prescriptions from recent events. Honduran President Manuel Zelaya told the U.N. General Assembly last month that the lesson of the crash was "the market's laws were demonic, satisfying only the few." Paraguayan President Fernando Lugo said the "market mechanism" and "immoral speculation" were a mistake. Brazilian President Luiz Inácio Lula da Silva Lula added that speculators have "spawned the anguish of entire peoples" and Brazilians needed "indispensable interventions by state authorities."

We have been here before. Development economics—the study of how poor countries can become rich—was forever cursed by the timing of its birth after the Great Depression. That gave development economics a bias toward relying on governments, rather than markets, to create growth. The early development economists ignored a century and a half of European and North American development through individual enterprise, remembering only that their governments forcefully intervened to stimulate output during the 1930s.

> Poor countries are learning the wrong lessons from the crisis.

What is widely agreed to be the seminal article in development economics appeared in 1943, calling poor countries "depressed areas." The Economic Journal article by Paul Rosenstein-Rodan, "Problems of Industrialization of Eastern and South-Eastern Europe," concluded that a fourth of the population of these countries was unemployed, and the solution rested in ceding development to the state. Development comes from state-planned investment in all sectors at once, the "Big Push," not reliance on private investors: "An individual entrepreneur's knowledge of the market is . . . insufficient," because he cannot have all the data "available to the planning board."

Similarly, the U.N.'s Depression mindset prompted them to ask an expert commission led by Sir Arthur Lewis in 1950 to prepare a report on unemployment in underdeveloped countries. Its report concluded that "economic progress depends to a large extent upon the adoption by governments of appropriate . . . action," and that political leaders must have a strategy for such growth, reflecting "the facts of each particular case."

Few at the time disagreed. Oxford economics professor S. Herbert Frankel wrote a rare protest in 1952. He believed poor, ordinary people had "peculiar aptitudes for solving the problems of their own time and place," a confidence later vindicated by homegrown success in Botswana, the East Asian tigers, India, Chile, Turkey and China.

Lewis later received a Nobel Prize in Economics. Poor Frankel was basically forgotten.

Development economics still bears the scars of the Depression. A prominent World Bank Growth Commission concluded in May that "fast, sustained growth does not happen spontaneously. It requires a long-term commitment by a country's political leaders," and "each country has specific characteristics and historical experiences that must be reflected" in the leaders' "growth strategy." Some at the U.N. still recommend the discredited Big Push strategy of state-planned investment.

How much poverty has endured because individual entrepreneurs were shunned in favor of the likes of the $5 billion state-owned Ajaokuta Steel Mill in Nigeria, which never produced a bar of steel? Or because African governments spend their time preparing World Bank-required national Poverty Reduction Strategy Reports instead of freeing space for innovators?

We will never know. But we do know that the free market has a long-run track record of creating prosperity—even with the occasional crash. The Depression's deceptive intellectual legacy is that development flows from all-knowing states rather than creative individuals. Here's hoping that the backlash to today's crash will not spawn another round of bad economics for the poor.

*Mr. Easterly is professor of economics at New York University, and author of "The White Man's Burden," (Penguin USA, 2006).*

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