BNA's
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ROUTE TO

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HIGHLIGHTS

See p. 60

November 10, 1988

PRESIDENT REAGAN SIGNED into law (PL 100-617) on November 5 a bill (S 2201) that will allow copyright owners to continue to control the rental of sound recordings. The new law extends the Record Rental Amendment of 1984 for an additional eight years. page 45

PATENT EXAMINER'S KNOWLEDGE of relevant prior art is not discoverable to prove inequitable conduct in a patent infringement action, the U.S. Court of Appeals for the Federal Circuit held November 1. In a case of first impression, the court held that it is no more appropriate to question the technical expertise of a patent examiner, a quasi-judicial officer, than it is to question a judge's law school education or judicial experience. page 45

SUPREME COURT WILL REVIEW the conflict among the circuits over the proper interpretation of the Copyright Act's "work made for hire" provisions. After declining to review a Fifth Circuit decision on the issue last spring, the Court on November 7 agreed to review a case out of the District of Columbia Circuit concerning copyright ownership of a sculpture depicting homeless people. page 46

ITC INTERIM RULES have been issued to implement the changed procedure for excluding infringing imports under Section 337 of the Tariff Act of 1930, put in place by the new trade bill. In addition to amending its adjudicative and enforcement rules, the ITC on November 4 and 7 also proposed new rules on the posting and forfeiture of temporary relief bonds, and on a duty of candor for complainants in §337 actions. page 47

PLUG MOLDING STATUTES have provided the Supreme Court with its latest opportunity to revisit the *Sears/Compco* doctrine and consider whether federal patent law preempts state prohibitions in this field and permits unrestricted copying of unpatented articles. This case pits a decision of the Florida Supreme Court, striking down a Florida plug molding statute, against a decision of the Federal Circuit which sustained a California plug molding statute. page 49

TRADEMARK OWNERSHIP passes with ownership of the building or business with which the mark is associated, the U.S. District Court for the Northern District of Illinois determined October 24. Holding that the tenant and operator of the "Esquire" theatre building held only an implied right to use the "Esquire" mark during its tenancy, the court ruled that the decision of the building's owner to lease rather than occupy and operate the theatre building does not show a failure to use the mark. page 50

CLASS PATENT WAIVER of the government's rights in certain inventions made under government contracts or cooperative agreements is the subject of a November 4 proposed rule from the Energy Department. The purpose of the class waiver is to expedite the retention of rights by the private sector to inventions made under federally funded research and development. page 51, 56

AIPLA MEETING in October examined changes in ITC and Canadian practice. page 52

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TEXT

ENERGY DEPARTMENT PROPOSED RULES ON CLASS PATENT WAIVERS

53 FR 44602

DEPARTMENT OF ENERGY

10 CFR Part 785

Class Patent Waiver

AGENCY: Department of Energy.

ACTION: Proposed rule.

SUMMARY: The Department of Energy (DOE) today proposes a rule which would provide for a class waiver of the Government's rights in certain inventions made under contracts, grants, or cooperative agreements of DOE. The purpose of this class waiver is to maximize and expedite, to the extent permitted by law, the retention of rights to inventions made in the performance of federally-funded research and development contracts, grants, or cooperative agreements by the private sector. Generally, pursuant to 42 U.S.C. 2182 (1982) and 42 U.S.C. 5908 (1982), for contracts, grants, agreements or other arrangements with DOE for research, development or demonstration work, with entities other than small business or nonprofits, title in inventions vests in the Government, unless the Government waives its rights in conformity with the provisions of these statutes. This proposed rule provides for a class wiaver in two categories:

(1) A class advance waiver (i.e., waiver at the time of contracting) of the Government's rights in inventions arising from contracts with domestic large business contractors, other than management and operating contractors generally referred to as GOCOs; and

(2) A class waiver of the Government's rights in identified inventions arising from contracts with domestic large business contractors, including management and operating contractors.

The proposed class waiver is subject to requirements, limitations, terms and conditions as provided in the proposed rule, and is intended to be implemented by simplified procedures requiring contractor certification of compliance with the requirements, terms and conditions of the class waiver. Where the class waiver is not applicable, contractors may still seek patent waivers on a case-by-case basis in accordance with established practices.

DATES: Written comments must be received on or before January 9, 1989.

A public hearing will be held on December 13, 1988 at 9:00 a.m. Requests to present oral statements must be received no later than November 30, 1988.

ADDRESSES: Written comments (three copies) and requests to speak at a public hearing must be addressed to: Richard E. Constant, Assistant General Counsel for Patents, GC–42, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

The hearing will be held at DOE Headquarters, 1000 Independence Avenue, SW., Washington DC, Room 1E–245.

FOR FURTHER INFORMATION CONTACT: Richard A. Lambert, Office of Assistant General Counsel for Patents, 1000 Independence Avenue, SW., Washington, DC 20585. Telephone (202) 586–2802.

SUPPLEMENTARY INFORMATION:

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IV. Review Under Regulatory Flexibility Act
V. Review Under National Environmental Policy Act
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VII. Federalism
VIII. Opportunities for Public Participation
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C. Conduct of Hearing

I. Background

Normally, for contracts, grants, agreements, or other arrangements with DOE for research, development or demonstration work with entities other than domestic small businesses or nonprofit organizations, title in inventions vests in the Government, pursuant to the Atomic Energy Act of 1954 (42 U.S.C. 2182 (1982)) and the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908 (1982)), unless the Government waives its rights in inventions in conformity with the provisions of these statutes. Title 35 U.S.C. 202 (1982) (Pub. L. 96–517, as amended by Pub. L. 98–620), generally permits domestic small business firms and domestic nonprofit organizations to elect to retain title in inventions made under funding agreements with the Federal Government. Accordingly, this notice concerns only domestic large, for profit, businesses, not covered by 35 U.S.C. 202, as to which the right to title to inventions is governed by the Atomic Energy and Nonnuclear Acts, subject to the guidance to agencies contained in the President's Memorandum on Government Patent Policy of February 18, 1983, as referenced in Executive Order 12591, dated April 10, 1987.

The Memorandum of Government Patent Policy directs that:

> To the extent permitted by law, agency policy with respect to the disposition of any invention made in the performance of a federally-funded research and development contract, grant, or cooperative agreement

> award shall be the same or substantially the same as applied to small business firms and nonprofit organizations under Chapter 38 of Title 35 of the United States Code.

With the overall goal of incorporating the results of the Department's research, development, and demonstration programs into the mainstream of American commerce consistent with the objectives of the President's patent policy and in accordance with the authority of 42 U.S.C. 2182 (1982) and 42 U.S.C. 5908 (1982), DOE proposes that it is in the best interests of the United States and the general public to grant a class waiver as provided in the proposed regulation.

The proposed rule provides for a class waiver in two categories:

(1) Class advance waiver of the Government's rights in inventions arising from contracts with domestic large business contractors other than Management and Operating Contractors.

(2) Class waiver of the Government's rights in identified inventions arising from contracts with domestic large business contractors including Management and Operating Contractors.

The Department reserves the right to grant additional class waivers as deemed appropriate in the public interest. Consideration was given to granting an additional class waiver covering inventions falling within certain exceptional circumstances technologies, which would have provided an exclusive license to recipients of funding agreements with domestic small businesses and nonprofit organizations for fields of uses outside the specified exceptional circumstances.

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However, the applicable class of inventions and potential waiver recipients is not deemed to be sufficiently broad to justify at this time the grant of such a class waiver. Requests for waiver of the Government's rights in such technologies may continue to be made, on a case-by-case basis, in accordance with established DOE waiver policies and procedures.

Certain areas in the national interest are excluded from the scope of these waivers. The exclusions are generally as follows: inventions arising under international agreements or treaties; weapons-related inventions; inventions made under agreements funded by DOE's naval nuclear propulsion program; classified or sensitive inventions; uranium enrichment inventions; inventions relating to storage and disposal of civilian high-level nuclear waste or spent nuclear fuel; and inventions falling within other class waivers granted to third parties by DOE.

Inventions arising under international agreements or treaties are excluded from the class waiver in order to avoid conflict with invention rights provisions of such agreements or treaties.

Weapons-related inventions are excluded from the class waivers for reasons involving nonproliferation of weapons, national security, conflicts of interest, management requirements of DOE's unique contractor operated weapons laboratories and in order that DOE may ensure prosecution of patent applications or statutory invention recordings on selected inventions in which the Government has a strong interest in establishing license rights.

Classified and sensitive inventions are also excluded from the scope of the class waivers for the reasons noted above for weapons related inventions. In addition, the restricted status of such inventions usually continues for many years, during which any present plans of a contractor to commercialize the inventions are subject to change.

In the case of uranium enrichment, the technology at present is exclusively under Government control with the Government being the only legal customer for the technology. Therefore, the rationale for establishing private incentives is lessened if not eliminated. Furthermore, DOE currently has a requirement to preserve the transferability of this technology to the private sector. In order to retain a transferable package of intellectual property rights, DOE retains title in this area.

Regarding technology for storage and disposal of civilian high-level nuclear waste or spent nuclear fuel, since the program is funded through special fees levied on the utility industry, Government retention of patent rights preserves the Government's flexibility to grant licenses to utilities as appropriate, or to solicit utility industry participation in rights allocations. Further, since the Government has a statutory mandate to develop the technology to the point of commercialization, incentives inherent in the patent system are not the driving mechanism to promote development of this technology.

However, for one of the excluded technologies, i.e., storage and disposal of civilian high-level nuclear waste or spent nuclear fuel and possibly for excluded technologies that may in the future be so designated, a contractor may elect to retain an exclusive license in all fields of use outside the excluded technology where the contractor can demonstrate that the invention has such an outside use, and specifically identifies such use as one it will commercialize within three years. An example of such an outside use is use of nuclear waste disposal technology for disposal of nonradioactive toxic chemical wastes.

Inventions covered by existing or future class waivers to third parties, e.g., DOE's class waivers covering third party use of DOE facilities, are excluded from the class waiver covering identified inventions for large business contractors, in view of the overriding DOE interest in promoting third party use of such facilities and to avoid invention rights conflicts that might arise from conflicting class waiver provisions.

In addition, similar to DOE's authority to declare "exceptional circumstances" under 35 U.S.C. 202(a) the Secretary of Energy reserves the right to designate further exclusions to this class waiver, as deemed necessary in the national interest.

Of course, contractors may request a waiver of rights to an invention, including those excluded from the scope of this class patent waiver, pursuant to DOE's existing waiver policies and procedures.

Implementation of the class waiver proposed herein is intended to be made using simplified procedures requiring certifications by contractors regarding matters such as its intent to commercialize a particular invention, including submission of general plans for commercialization, (itself or through licensees) within three years (with a right to seek extension of such three-year period, in two year intervals, if contractor can demonstrate to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention), and its willingness to bear patent costs, followed by review and certification by DOE that the conditions of the particular class waiver have been made, e.g., a cost-sharing of 20% (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs). The proposed class waiver will result in significant reductions in the paperwork burdens imposed on contractors seeking a DOE patent waiver as compared to current policies, which require a waiver petitioner to submit considerably greater amounts of information in support of a waiver request.

(1) Class Advance Waiver

Subject to exclusions as noted above, the class advance waiver applies:

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1. To contractors which are domestic large businesses (i.e. not qualifying as small businesses or nonprofit organizations under 35 U.S.C. 202 (1982) engaged in research, development, or demonstration work under a DOE contract, except contracts for management or operation of contractor-operated research, production or weapons facilities (GOCO);

2. Where the contract requires 20% cost sharing by the contractor (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs);

3. Where the contractor agrees to commercialize any elected invention itself or through its licensee(s) within a three-year time period from the date of disclosure of the invention to DOE, subject to extension of the time period for commercialization, in two year intervals, so long as contractor can demonstrate to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention; and

4. Where DOE certifies the application of the waiver to the contract.

Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5908 (1982)), in establishing the patent waiver authority, provided four objectives that the Secretary or his designee is to seek to accomplish in making waiver determinations. In addition, eleven specific factors are to be considered at the time of contracting in making such determinations. DOE has harmonized these provisions with section 152 of the Atomic Energy Act of 1954, 42 U.S.C. 2182 (1982) so that waivers are evaluated under these criteria regardless of the technology under which an invention is made. Within

these statutory structures, DOE's waiver policy has been used flexibily. DOE has granted many advance waivers both to large corporations and, prior to the passage of The Patent and Trademark Amendments of 1980, Pub. L. 96–517, section 7, 94 Stat. 3016, to small businesses and universities. Certain consistent fact patterns have formed the basis for granting advance waivers to large businesses on a case-by-case evaluation. These patterns are utilized in this class advance waiver in accordance with the statutes.

DOE has generally granted waivers to large business contractors who cost share a minimum of 20% (not including waived fee) of the contract costs. This level of cost sharing has evolved over several years of waiver experience and has been shown to be an excellent indication of whether a research project fits within a corporations' long range plans and of the corporate interest in commercializing the technology which is the subject of the contract. Cost sharing establishes a corporate commitment by the contractor to commercialize the technology. Establishing a 20% cost sharing standard for this class waiver recognizes the experience gained from previous waivers and will simplify the process by which large business contractors can obtain advance waivers. Further, DOE has found having 20% cost sharing effectively extends its ability to carry out its programmatic mission. The 20% cost sharing requirement has been found to be an effective tool to combine corporation research interest with Government programs, thereby leveraging Government research funds and providing technology transfer into commercial application. This promotes the commercialization of inventions made under these contracts and serves to make the benefits of DOE's energy research, development, and demonstration programs widely available to the public in the shortest practicable time. Over DOE's several years of experience using 20% cost-sharing as a prime consideration for grant of an advance patent waiver, we are not aware of any prospective contractor declining to contract with DOE as a result of 20% cost-share requirement for an advance waiver. To provide flexibility, however, the 20% cost sharing required for this class waiver may be changed to another level if it is determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs. The public is specifically invited to provide comments regarding the appropriateness of the 20% cost-sharing level as a precondition to a class advance waiver. If any member of the public wishes to comment on this point, we would appreciate his or her views on the appropriate cost-share level for an advance waiver, with reasons therefor.

The other requirement of this class waiver, that the contractor agree to commercialize any elected invention (itself or through its licensees) within a three year time period (subject to extension if contractor can show that it or its licensee(s) is actively pursuing commercialization of the invention) serves to foster and assure expeditious pursuit of commercial utilization of waived inventions by the contractor. Three years appears to be a reasonable time period for an entity acting in good faith to proceed to effect commercialization of a typical invention. For those inventions which may require longer time periods for commercialization in view of, for example, the need for extensive development efforts prior to effecting commercialization, the three year time period may be extended, in two year intervals, so long as contractor can demonstrate to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention.

DOE's ten years of experience in granting advance waivers to contractors who have cost shared has resulted in no indication to DOE of an adverse impact on competition. No such adverse impact is foreseen from this class waiver. Waived inventions will be subject to a license to the Government and DOE will have the right to require periodic reports on the contractor's utilization, or efforts at obtaining utilization, of the invention. Further as a condition of this waiver, DOE shall have the right to exercise its march-in rights and require the contractor to license a waived invention if DOE determines that the contractor is not making reasonable efforts to utilize the invention, or alternatively, if the practice of the invention by the contractor or its assignee or licensee has tended substantially to lessen competition or result in undue concentration in any line of commerce to which the technology of the invention relates. An additional march-in right provides for automatic termination of the waiver as it relates to a particular invention and reversion of title in the invention to the Government if the invention is not commercialized within three years (subject however to extension of the three-year period for commercialization if the contractor can demonstrate to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention). Concomitant with this class advance waiver, DOE is also granting a class waiver to identified inventions to large business contractors, including management and operating contractors of DOE Government-owned facilities (GOCOs), where the contractor agrees to commercialize the invention, either itself or through licensees within a three-year time period. These two categories complement each other to permit the large business contractor, including GOCO contractors, to acquire title to all inventions (except for those imbued with the national interest as set forth herein) in which the contactor has plans for commercialization, either itself or through licensees. This class waiver will significantly act to elicit private risk capital and promote commercial utilization of inventions made under DOE's research, development, and

demonstration programs and thereby make the benefits of these programs widely available to the public in the shortest practicable time.

(2) Class Waiver of Identified Inventions

Subject to exceptions as noted above, the class waiver of patent rights to identified inventions applies to inventions made by contractors who are domestic large businesses (i.e., entities not qualifying as small business firms or nonprofit organizations under 35 U.S.C. 202 (1982) engaged in research, development, or demonstration work under a DOE funding agreement, including contractors for the management and operation of DOE research, production or weapons facilities (GOCO), where:

(1) The contractor agrees to commercialize the invention itself or through its licensees within a three-year time period from the date of waiver is effective as to the invention. Three years appears to be a reasonable time period for an entity acting in good faith to proceed to effect commercialization of a typical invention. The three-year time period for commercialization is subject to extension, in two-year intervals, so long as contractor demonstrates to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention. For purposes of this regulation, "commercialize" shall mean to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations

available to the public on reasonable terms;

(2) The contractor reports the invention and elects to retain the rights therein within the times provided in the contract for reporting inventions and requesting greater rights, respectively (however, normally the waiver will not apply to inventions which DOE has advertised as being available for licensing) and agrees to file, prosecute, and maintain any and all patent applications and patents on the invention at its own expense, unless, in the case of GOCO contractors, special contractual provisions are negotiated;

(3) The invention is not, at the time of the request for waiver, developed to the point of commercialization by the Government and further development of the invention is not being funded and is not intended to be funded by the Government. Among DOE's statutory considerations for waivers are consideration of the extent to which the Government intends to further develop to the point of commercial utilization the results of the contract effort, and consideration of the extent to which a waiver is a reasonable and necessary incentive to call forth private risk capital for the development and commercialization of the invention. Limiting the class waiver to inventions not being funded and not intended to be funded by the Government encourages expenditure of private risk capital for development and commercialization of an invention, and affords appropriate weight to the foregoing considerations. For purposes of this waiver, an invention is not further funded if Government funding is not being, and is not intended to be, directed at the further development of the invention or the enhancement of the invention in a manner beneficial to commercial applications of the invention. This does not include insignificant amounts of fnding for minor modification of the invention or use of the invention incidental to other work. On the other hand, further funding would clearly exist where work is directed toward actually reducing an invention to practice or developing the invention in a manner which improves its performance or enhances its value in commercial applications. To implement this class waiver, the contractor is required to certify that the invention has not been developed to the point of commercialization and that, to the best of contractor's knowledge and belief, further development of the invention is not being funded and is not intended to be funded by the Government. Since this information is generally within the knowledge of the requestor, certifying as to such matters should present no undue burden on the contractor; and

(4) The waiver is certified by DOE to be applicable to the invention.

For the purposes of this waiver, contractor means either a prime contractor or a subcontractor. The waiver does not give a prime contractor or subcontractor rights in the other's inventions.

Section 9 of the Federal Non-nuclear Energy Research and Development Act of 1974, 42 U.S.C. 5908 (1982), in establishing the patent waiver authority, provided four objective that the Secretary or his designee is to seek to accomplish in making waiver determinations. In addition, specific statutory factors are to be considered in making these determinations with respect to identified inventions. DOE has harmonized these provisions with section 152 of the Atomic Energy Act of 1954, 42 U.S.C. 2182 (1982), so that waivers are evaluated under these criteria regardless of the technology under which an invention is made. DOE has granted many identified invention waivers over the past ten years and the experience therefrom is applicable to the present class waiver. In general, large business contractors are selected for a research, development, or demonstration contract because of their technical expertise in the subject matter of the contract. Providing the contractor with title to inventions made under DOE contracts should encourage a commitment to commercialization and foster the application of private risk capital for development and manufacture of inventions.

Regarding GOCO contractors, the Department of Energy (DOE), unlike most other Government agencies, employs contractors to manage and operate certain of its major research, production and weapons facilities. The following principles, as set forth by the Secretary of Energy, provide the policy framework for these management and operating (GOCO) contracts:

(1) The Government retains responsibility for overall program management and project technical direction while the contractor is responsible for the day-to-day management of the work;

(2) The Government and contractor have an identity of interest in the mission being pursued;

(3) The parties intend a long-term close relationship;

(4) The Government assumes virtually all financial risk;

(5) The contractor is hired to manage;

(6) The contractor broadly supports the performance of Government functions by executing programs of national significance on behalf of the Government; and

(7) The Government ultimately is responsible for security, health and safety and the proper use of public funds.

These contractor-operated Government facilities have for some forty years benefited DOE and its predecessor agencies in carrying out agency research, development, and demonstration (R,D&D) programs. The GOCO facilities have, in great measure, had a remarkable record of scientific and technical success. This success is due, in part, to the unique contractual relationship that exists between DOE and its GOCOs; viz., the dedication of both technical and administrative skills of a private organization to a significant

Federal mission in a close, long-term, cooperative relationship.

Most of the inventions made under research and development activities at the GOCO facilities require additional development before they are available in the commercial marketplace. This is because many of the GOCO inventions are founded upon basic or advanced research. Additionally, many of these inventions are conceptual in nature and are on a labortory or proof-of-principle scale. Scale-up to a commercial size demonstration of the inventive concept is often a prerequisite to negotiating royalty-bearing licenses. Finally, many of the inventions arising out of DOE's energy research will require substantial capital in order to translate the invention into commercial reality; such costs, for example, include further engineering, design, start-up and marketing.

A class waiver of the Government's rights in identified inventions as set forth herein will create sufficient exclusive rights in these inventions to bring forth private risk capital expeditiously to promote and move the technology into the commercial marketplace and thereby make the benefits of DOE's programs widely available to the public in the shortest practicable time. This would satisfy the broad objectives of section 9 of the Federal Non-nuclear Act, 42 U.S.C. 5908 (1982), while being in keeping with the ultimate objective of the Presidential Memorandum.

Furthermore, the grant of a class waiver of identified inventions as set forth herein would provide an effective mechanism for achieving technology transfer of energy-related technology into the mainstream of American commerce by bringing a focused

attention and stronger commitment on the part of the Department's GOCO contractors to this mission objective. Permitting these contractors to retain title to a broad range of important energy-related technologies should enhance the technology transfer initiative of the Department.

It is recognized that the various GOCO contractors have diverse interests and needs requiring flexibility in the implementation of this class waiver. Therefore, approaches which ensure that the needs of each GOCO contractor are met as well as serving the best interests of the United States and the general public must be tailored for each GOCO contract. Factors to be considered for such alternative approaches may include, for example, the willingness of the GOCO contractor to use all or a portion of royalties received from licensing of waived inventions for further research at the facility, and the willingness to assign over title to waived inventions to a successor contractor upon termination of the contract. Adequate provisions must be included to protect against a potential contractor conflict of interest as well, commensurate with the allocation of patent ownership and use of royalty income. Appropriate contractual provisions reflecting these concerns must be approved by the General Counsel or designee, and must be included in each GOCO contract in order for the GOCO contractor to qualify for this class waiver.

Granting this waiver should have no adverse impact on competition. Making title to inventions available to the contractor in technologies in which the contractor has plans for commercialization, either itself or through licensees, is consistent with DOE's past practices and will not only ensure the commercialization of the invention but enhance competition. The waiver will be subject to a license to the Government and DOE will have the right to require periodic reports of the contractor's utilization, or efforts at obtaining utilization, of the invention. Further as a condition of this waiver, DOE shall have the right to exercise its march-in rights and require the contractor to license a waived invention if DOE determines that the contractor is not making reasonable efforts to utilize the invention, or alternatively, if the practice of the invention by the contractor or its assignee or licensee has tended substantially to lessen competition or result in undue concentration in any line of commerce to which the technology of the invention relates. In addition, the waiver is automatically terminated if the contractor cannot demonstrate to the satisfaction of DOE that the invention has been commercialized within three-years of the disclosure of the invention to DOE, or if no extension of the three year period for commercialization is obtained. Concomitant with this waiver to identified inventions and in accordance with the above statutory authority, DOE is also granting a class advance waiver to domestic large business contractors that are not management or operating contractors, where the contractor agrees to cost share 20% of the contract effort (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs). These two categories complement each other to permit the large business contractor to acquire title to all inventions (except for those inbued with the national interest as set forth herein) in which the contractor has a commitment to commercialization. These two categories will significantly act to elicit private risk capital and promote commercial utilization of inventions made under DOE's research, development, and demonstration programs and management and operating contracts and thereby make the benefits of these programs widely available to the public in the shortest practicable time.

Certain inventions made by the contractor prior to the grant of this class waiver may be important to the contractor's commercialization efforts. While identified waiver requests could be made by the contractor for greater rights, on each of these inventions, it is desirable to reduce the paper work associated with processing waiver requests for these inventions. Additionally, expedited waiver processing would permit the earliest rapid start-up of commercialization and technology transfer programs by contractors by insuring a supply of inventions for these activities immediately upon the grant of the class waiver. Accordingly, the scope of this waiver shall also include inventions made by contractor (or if a GOCO, its predecessor) on which a timely filed identified waiver request is pending as of the effective date of this waiver. As noted earlier, the waiver shall normally not apply to any invention which DOE has advertised as being available for licensing.

As a condition of the waiver, the contractor shall provide to DOE on a DOE-approved form a duly-executed instrument fully confirmatory of all rights retained by the Government for each invention as to which the contractor retains rights pursuant to this waiver. The contractor will bear the costs of patent prosecution and maintenance unless, for a GOCO contractor, special contractual provisions are negotiated.

The waiver to the identified class of inventions is in the best interests of the United States and the general public, in accordance with the objectives to be obtained and the determinations to be made under DOE statutory waiver policy. It should encourage the participation of contractors in DOE programs and provide for the commercialization of DOE developed technology in the shortest practicable time.

Accordingly, in view of the statutory objectives to be obtained and the factors to be considered under DOE's statutory waiver policy, all of which have been considered, it is proposed

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that a waiver of the class of inventions identified above and under the situations described above will best serve the interests of the United States and the general public.

II Section-by-Section Discussion of Proposed Rule

Section 785.1 of the regulation defines the scope of the class waiver of the Government's U.S. and foreign patent rights in inventions arising from contracts with domestic large business contractors. Section 785.1(b) is directed to a class advance waiver. Generally, this class advance waiver is applicable to recipients of DOE contracts (including grants and cooperative agreements) with domestic large businesses, (other than GOCO contractors) where the contract requires 20% cost sharing by the contractor (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs), and where the contractor agrees to commercialize an elected invention (itself or through licensees) within a three year time period (subject to extension so long as contractor can demonstrate that it or its licensee(s) is actively pursuing commercialization of the invention).

Section 785.1(c) is directed to a class identified invention waiver, which generally applies to large business contractors, including GOCO contractors. The waiver is applicable generally to inventions which the contractor agrees to commercialize within a three-year time period, subject to extension as above, when such inventions have not been developed to the point of commercialization by the Government, and there is no further funding, nor plans for further funding of the invention by the Government.

Section 785.2 provides for exclusion of certain technologies from the class waiver in the national interest. Presently, excluded technologies include uranium enrichment technology, storage and disposal of civilian high-level nuclear waste and spent nuclear fuel technology, classified inventions, and inventions which are sensitive under section 148 of the Atomic Energy Act of 1954, 42 U.S.C. 2168 (1982). In addition, contracts and inventions under international agreements or treaties in existence or to be entered into in the future are also excluded from this waiver, as are all contracts and inventions funded by DOE's naval nuclear propulsion programs or by DOE's weapons programs. However, for inventions related to storage and disposal of civilian high-level nuclear waste and spent nuclear fuel, the contractor may elect to retain an exclusive license in fields of use outside such technology where the contractor specifically identifies such fields of use as uses it will commercialize within three years.

Section 785.3 addresses terms and conditions for class waivers, including a paid-up Government license, march-in rights, and requirements that patent costs be undertaken by the contractor. Section 785.4 provides for implementation of the class waiver by simplified procedures requiring certification by the contractor and DOE as to applicabiliy of the class waiver.

III. Review Under Executive Order 12291

Section 3 of Executive Order (E.O.) 12291 (46 FR 13193, February 19, 1981) requires that DOE determine whether a rule is a "major rule," as defined by section 1(b) of E.O. 12291, and prepare a regulatory impact analysis for each major rule. DOE has determined that the proposed rule does not meet the E.O. 12291 definition of a major rule as one likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, a regulatory impact analysis is not required.

Pursuant to section 3(c)(3) of E.O. 12291 these rules were submitted to the Director of OMB for a ten-day review. The Director has concluded his review under that Executive Order.

IV. Review Under Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612 (1982), requires, in part, that an agency prepare an initial regulatory flexibility analysis for any rule, unless it determines that the rule will not have a "significant economic impact" on a substantial number of small entities. The proposed rule concerns class patent waivers directed primarily at entities that are not small businesses, since there is separate statutory authority governing disposition of invention rights of Government contractors that are small businesses. Therefore, as required by section 603(b), DOE certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

V. Review Under National Environmental Policy Act

DOE has determined that the proposed rule is not a major Federal action with significant environmental impact and does not affect the quality of the environment. Consequently, the proposed rule does not require preparation of an Environmental Assessment or Environmental Impact Statement under the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.* (1982).

VI. Review Under Paperwork Reduction Act

The reporting requirements contained in this proposed rule have been submitted to OMB for approval under the Paperwork Reduction Act.

VII. Federalism

Executive Order (EO) 12612 requires that regulations or rules be reviewed for any substantial direct effects on States, on the relationship between the national government and States, or the distribution of power and responsibilities among various levels of government. If there are sufficient substantial direct effects, then EO 12612 requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a regulation or a rule.

The principal impact of today's regulation, when finalized, will be to speed up waivers of government patent rights to private entities. The regulation will not have any effect on the States, the relationship between the States and Federal government, or the distribution of power and responsibilities among various levels of government.

VIII. Opportunities for Public Participation

Section 501(c)(1) of the Department of Energy Organization Act, 42 U.S.C. 7191(c)(1) (1982), provides that if the Secretary determines that a substantial issue of fact or law exists or that a proposed rule is likely to have substantial impact on the Nation's economy or on large numbers of individuals or businesses, an opportunity for oral presentation of views, data, and arguments shall be provided. To preclude any issue in this regard, such an opportunity will be provided.

A. Written comment procedures. Interested parties are invited to participate in this rulemaking by submitting views, data, or arguments with respect to the proposal set forth in this notice to Richard E. Constant, Assistant General Counsel for Patents,

Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585. The comments and the outside of the envelope should be identified with the designation, "Docket No. GC88–2." Three copies of the comments should be submitted.

All comments received by January 9, 1989 and other relevant information will be considered by DOE before final action is taken regarding the proposed regulations.

B. Public hearing. DOE has determined to hold one public hearing on this proposal. The time and place of the public hearing is indicated at the beginning of this notice.

Any person who has an interest in the proposed rulemaking or who is a representative of a group of persons that has an interest in this rulemaking may make a written request for an opportunity to make an oral presentation. Such a request should be directed to the address given at the beginning of the preamble and must be received by the date specified at the beginning of this notice. Requests may be hand-delivered between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. Requests should be marked as for written comments, with the additional notation "Request to Speak."

The person making the request should briefly describe the interest concerned and, if appropriate, state why that person is a proper representative of a group with such an interest, give a concise summary of the proposed oral presentation, and provide a phone number where the person or group may be contacted through January 9, 1989.

Each person selected to be heard at the public hearing will be notified by

December 6, 1988. Witnesses presenting oral testimony must bring seven copies of their statements to the hearing.

In the event any person wishing to testify cannot provide seven copies, alternative arrangements can be made with the hearing coordinator in advance of the hearing by so indicating in the letter requesting an oral presentation or by calling (202) 586–2802.

C. Conduct of hearing. DOE reserves the right to select the persons to be heard at the hearing, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearing. The length of each presentation shall be limited to 20 minutes.

A DOE official will be designated to preside at the hearing. This will not be a judicial or evidentiary type hearing. Questions may be asked of speakers only by those conducting the hearing, and there will be no cross-examination of persons presenting statements. Any decision made by DOE with respect to the subject matter of the hearing will be based on all information available to DOE. At the conclusion of all initial oral statements at the hearing, each person who has made an oral statement will be given the opportunity to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

Any person wishing to ask a question at the hearing may submit the question, in writing, to the presiding officer. The presiding officer will determine whether the question is relevant, and whether the time limitations permit it to be presented for answer.

Any additional procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer.

A transcript of the hearing will be made and the entire record of the hearing, including the transcript, will be retained by DOE and made available for inspection at the DOE Freedom of Information Office, Room 1–E–152, 1000 Independence Avenue, SW., Washington, DC, between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday except Federal holidays. Any person may purchase a copy of the transcript from the court reporter.

The public hearing may be cancelled if no public testimony is scheduled in advance. In the event the hearing is cancelled, DOE will make every effort to publish an advance notice of such cancellation in the Federal Register.

List of Subjects in 10 CFR Part 785

Inventions, Licenses, Patents and waivers.

In consideration of the foregoing, Part 785 of Title 10 of the Code of Federal Regulations is proposed to be added as set forth below.

Issued in Washington, DC, October 28, 1988.

Eric J. Fygi,

Acting General Counsel.

PART 785—CLASS PATENT WAIVER

Sec.
785.1 Scope of waiver.
785.2 Limitations.
785.3 Terms and conditions.
785.4 Procedures.

Authority: Department of Energy Organization Act, section 301, 42 U.S.C. 7151 (1982); Federal Nonnuclear Energy Research and Development Act of 1974, section 9, 42 U.S.C. 5908 (1982); Atomic Energy Act of 1954, section 152, 42 U.S.C. 2182 (1982); President's Memorandum on Government Patent Policy (1983).

§ 785.1 Scope of waiver.

(a) The Department of Energy, hereinafter "DOE," waives its rights under section 152 of the Atomic Energy Act of 1954, 42 U.S.C. 2182 (1982), and section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974, 42 U.S.C. 5903 (1982), subject to the limitations and provisions contained herein, (1) in advance, with respect to all inventions and discoveries arising from certain contracts as specified herein, including grants and cooperative agreements, with domestic large business contractors other than Management and Operating Contractors (as defined in 48 CFR 17.601) (hereinafter M&O contractors), and (2) with respect to identified inventions arising from contracts, grants, and cooperative agreements, with domestic large business contractors, including M&O contractors.

(b) The class advance waiver applies to contractors which are domestic large businesses (i.e., not qualifying as small businesses or nonprofit organizations under 35 U.S.C. 202 (1982) engaged in research, development, or demonstration work under a DOE contract, except contracts for management and operation of contractor-operated research, production or weapons facilities, where:

(1) The contract requires 20% cost sharing by the participant (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs);

(2) The contractor agrees to commercialize any elected invention, itself or through its licensees, within a three year time period from the date of disclosure of the invention to DOE, subject to extension of the time period for commercialization, in two year intervals, so long as contractor demonstrates to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention. For purposes of this regulation, "commercialize" shall mean to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system, and, in each case under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms; and

(3) DOE, upon review of the contract and relevant facts, certifies that the wavier applies to the contract.

(c) The class identifed invention waiver applies to inventions made by contractors who are domestic large businesses (i.e. not qualifying as small businesses or nonprofit organizations under 35 U.S.C. 202 (1982)) engaged in research, development or demonstration work under a DOE contract, including a contract for management and operation (M&O contract) of a DOE research, production or weapons facility, where:

(1) The contractor agrees to commercialize the invention itself or through its licensees within a three year time period from the time the waiver is effective as to the invention, subject to extension of the time period from commercialization, in two year intervals, so long as contractor demonstrates to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention;

(2) The contractor reports the invention and elects to retain the rights therein, within the times provided in the contract for reporting inventions and requesting greater rights, and agrees to file, prosecute, and maintain any and all patent applications and patents on the invention at its own expense;

(3) The invention is not, at the time of the request for waiver, developed to the point of commercialization by the Government and the Government is not funding further development of the invention and has no intentions for further funding of the invention; and

(4) Upon review of the invention and relevant facts, DOE certifies the waiver is applicable to the invention.

(d) In order to expedite processing of previously filed waiver requests, the

scope of the identified invention waiver shall also include inventions made by the contractor (or, in the case of a Management and Operating Contractor, its predecessor) on which a timely filed identified invention waiver request in accordance with DOE's existing patent waiver regulations is pending as of the effective date of this waiver. However, the class waiver shall normally not apply to any invention which DOE has previously advertised as being available for licensing.

(e) Certain technologies, listed in § 785.2, have been excluded from the scope of this waiver in the national interest. However, with respect to inventions falling within the limitation specified in § 785.2(d), or the limitation specified in § 785.2(j) if so authorized by the Secretary, when the contractor demonstrates that the invention has a commercial use falling outside said limitation the contractor may elect to retain an exclusive license. The exclusive license will apply to all fields of use outside the said limitation where such fields of use are specifically identified by the contractor as uses it intends to commercialize within three years from the date of disclosure of the invention of DOE, (subject to extension of the time period for commercialization, in two year intervals, so long as contractor demonstrates to the satisfaction of DOE that it or its licensee(s) is actively pursuing commercialization of the invention in such field of use) and will include the right to grant sublicenses of the same scope. The exclusive license shall be subject to the same requirements, procedures, terms and conditions as provided herein for application of the waiver (including the royalty free right of the Government to practice inventions by or on behalf of the Government in such fields of use), except that the Government may file a patent application thereon, and retain title to any resulting patent. Upon the contractor's request, DOE may permit the contractor to file a patent application on behalf of the Government. Where the contractor requests the right to file a patent application on behalf of the Government, the contractor normally must bear the cost of preparing and prosecuting the patent application and maintaining any resulting patent at its private expense. Upon timely request by the contractor, DOE will make a determination as to whether an invention reported in accordance with the contract is covered by the limitations specified in § 785.2.

(f) DOE reserves the right to change the scope of rights available to contractors in later-identified exceptions under § 785.2(j).

(g) For purposes of this waiver, contractor means either a prime contractor or a subcontractor. The waiver does not give a prime contractor or subcontractor rights in the other's inventions. The waiver shall not affect any future waiver or any waiver previously granted. The advance waiver shall not apply to any contract which has been modified to reduce the cost share below 20% (or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs).

§ 785.2 Limitations.

The class waiver of this regulation does not include:

(a) Contracts and inventions under international agreements or treaties in existence or to be entered into in the future;

(b) Contracts and inventions funded by DOE's naval nuclear propulsion program or by DOE's weapons programs;

(c) Contracts and inventions relating to uranium enrichment (including isotope separation);

(d) Contracts and inventions relating to storage and disposal of civilian high level nuclear waste or spent nuclear fuel;

(e) Contracts and inventions relating to subject matter that is classified, or sensitive under section 148 of the Atomic Energy Act of 1954, 42 U.S.C. 2168 (1982);

(f) For identified invention waivers, any weapons related inventions;

(g) For identified invention waivers, inventions that occur under or are related to DOE's weapons related programs being conducted under contracts for the management and operation of facilities primarily dedicated to those programs;

(h) For identified invention waivers, inventions that are made under contracts for the management and operation of facilities primarily dedicated to naval nuclear propulsion or defense program production facilities;

(i) For identified invention waivers, those inventions covered by existing or future class waivers granted to third parties by DOE, e.g. the "work for others" class waiver;

(j) Any further exceptions that may, in the national interest, be designated by the Secretary in the future.

§ 785.3 Terms and conditions.

(a) The class advance waiver is conditioned upon the requesting contractor's accepting a Patent Rights clause in accordance with the Federal Acquisition Regulations and any applicable DOE regulations, as modified by DOE for any designated exceptions, including a paid-up Government license and march-in rights; utilization reporting requirements; a requirement of automatic termination of the waiver as it applies to a specific invention and reversion of title to the Government if the contractor cannot demonstrate to the satisfaction of DOE that it or its licensee(s) has commercialized the invention within these years from the date of disclosure of the invention to DOE, or obtained an extension to such three-year period for commercialization; a requirement that the contractor license

a waived invention if the practice of the invention by the contractor or its assignee or licensee has tended substantially to lessen competition or result in undue concentration in any line of commerce to which the technology of the invention relates; a requirement that prosecution and maintenance of an elected invention shall be at the sole expense of the contractor, regardless of any present or future interest that the U.S. Government may retain, so long as the contractor desires to retain title to the invention; and a requirement that the contractor shall provide DOE on a DOE-approved form a duly executed instrument fully confirmatory of all rights retained by the Government for each invention as to which the contractor retains rights pursuant to this waiver.

(b) The identified invention class waiver is conditioned upon the electing contractor's providing DOE on a DOE-approved form a duly executed instrument fully confirmatory of all rights retained by the Government, similar to the rights enumerated in § 785.3(a), for each invention in which the contractor retains rights pursuant to this waiver. In addition, for contracts for Management and Operation of Government Facilities, appropriate contractual provisions reflecting terms of implementation of this waiver must be approved by the General Counsel or designee, and must be included in each contract for the contractor to qualify for this class waiver. Such provisions may include clauses addressing, for example, conflict of interest matters, disposition of royalties, and willingness to assign title to waived inventions to a successor contractor. Unless special contractual provisions are negotiated, the contractor will normally bear the costs of patent prosecution and maintenance.

§ 785.4 Procedures.

(a) For an advance waiver, implementation of this class waiver is to be by a simple procedure which requires (1) a written request for an advance waiver by a contractor; (2) certification by the contractor regarding its intent to commercialize any elected invention itself or through its licensee(s) within three years from the date of disclosure of the invention to DOE, including a general statement of contractor's plans and intentions to so commercialize; and (3) certification by the contractor that it will bear the costs of patent prosecution and maintenance of waived inventions at its private expense.

(b) For an identified invention waiver, implementation of this class waiver is to be a simple procedure which requires (1) the contractor's reporting the invention with an election to retain rights in accordance with the class waiver (such election is to be within the time for requesting a waiver as provided in the contract and should identify the fields of use for which rights are requested if the invention falls within the scope of limitation § 785.2(d), or § 785.2(j) if applicable; (2) certification by the contractor that to the best of its knowledge the invention does not fall within international agreements or treaties of the U.S. Government; (3) certification by the contractor regarding its intent to commercialize the invention itself or through its licensee(s) within three years from the time this waiver is effective as to the invention, including a general statement regarding contractor's plans and intentions to so commercialize; (4) if the contract involves classified subject matter, certification by the contractors as to whether the invention is classified, or sensitive under section 148 of the Atomic Energy Act of 1954, 42 U.S.C. 2168 (1982); (5) certification by the contractor that the invention has not been developed to the point of commercialization and that to the best of contractor's knowledge and belief, further development of the invention is not being funded and is not intended to be funded by the Government; and (6) certification by the contractor that it will bear the cost of prosecuting and maintaining any patent applications or patents on the invention at its private expense, unless, if a Management and Operating Contractor of a Government facility, otherwise approved by the General Counsel or designee.

(c) For either an advance or identified waiver, the General Counsel or designee must review and certify as to whether the conditions of the waiver have been met. This includes, for an advance waiver, certification of meeting the requirement of 20% cost sharing (not including any waived fee) or such other level as may be determined by the General Counsel or designee to be warranted in view of specific mission, programmatic or statutory needs or, for an identified waiver, certification that the waiver is applicable to the reported invention. This function may be delegated to DOE patent counsel assisting the procuring activity under the direction of the General Counsel or designee.