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TO : Senate Special Committee on Aging
Attention: John Monahan

FROM : American Law Division

SUBJECT : Analysis of Government Use of Patented Pharmaceuticals

INTRODUCTION

Various questions have been raised concerning the government's possible use or manufacture of patented pharmaceuticals without the permission of the patent holder.[1] Foremost among these questions is what recourse the patent holder might pursue against the federal government. Directly related questions involve how such actions have been maintained and what factors have been considered by the courts in their resolution of such issues. This memorandum analyzes the remedy that a patent holder might have against the federal government if the federal government attempts to use the patent holder's pharmaceutical patent without his/her permission.

It appears that the fundamental recourse available to such a patent holder in this situation is specifically authorized by a federal statute which provides that the patent owner's remedy shall be an action against the United States in the United States Claims Court for the recovery of the "reasonable

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[1] Such a situation might arise through the federal government's attempt to reduce costs of federal drug purchase/reimbursement programs by "taking" the drug patent. However, during the term of the drug's patent, usually seventeen years, the law permits only the patent holder to produce or to license another manufacturer to produce the drug. The government might have another manufacturer produce the "single-source drugs" (chemical entities for which only the patented product is available) at a reduced cost. In such a situation, the government might be using/taking the patent without the permission of the patent holder and could be subject to an action brought by the patent holder. See, letter from John Monahan, Senate Special Committee on Aging, to Douglas Weimer, CRS (July 6, 1989).

and entire compensation" for such use.[2] The legislative development and the judicial application and interpretation of this statute are discussed below.[3]

BACKGROUND

It is well-established that, when a patent is granted for a discovery, it confers upon the patentee the sole rights to the patent (35 U.S.C. § 154(1982)) and that it cannot be used, taken, or appropriated by the government or its agent without just compensation (U.S. Const. amend V).[4] Courts and Congress have determined that the only remedy available under an eminent domain[5] taking of a license in a patent is through a specific federal statute which provides relief in the United States Claims Court (28 U.S.C. § 1498(1982)).[6] It has been held that section 1498 "authorizes the Government to take, through exercise of its power of eminent domain, a license in any United States patent."[7] This statutory remedy was enacted in 1910 in order to provide patent owners with recourse for reasonable compensation for the use of patents by the government without the license or the permission of the owner to use the patented discovery.[8] Although the statute has been modified various times, its primary remedy has remained constant.

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[2] 28 U.S.C. § 1498(a)(1982)(copy in Appendix).

[3] This memorandum summarizes several telephone discussions and a staff meeting between Douglas Weimer of the American Law Division and John Monahan of the Senate Special Committee on Aging.

[4] *See*, Rosenberg, *Patent Law Fundamentals* § 12.4[3](1988).

[5] The concept of eminent domain involves a "taking" by the sovereign government of private property for the public good. Such private property may be real or personal. *See*, *Boom Co. v. Patterson*, 98 U.S. 403 (1879). Examples of private property taken through eminent domain proceedings could involve real property, the franchise of a private corporation, or letters patent for a new invention. *See, e.g.*, *James v. Campbell*, 104 U.S. 356 (1882); *Hollister v. Benedict Mfg. Co.*, 113 U.S. 59 (1885).

[6] *Decca, Ltd. v. United States*, 640 F.2d 1156, 1166 (Ct.Cl. 1980).

[7] *Id.*

[8] Act of June 25, 1910, C. 423, 36 Stat. 851.

§ 1498. Patent and copyright cases

> **(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his *reasonable and entire compensation* for such use and manufacture. (emphasis added)**

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It appears that this statute ("section 1498") would probably govern remedies pursued by pharmaceutical manufacturers who seek relief against unauthorized government use of their patents. Thus, the patent holder(s) would bring an action against the government in the United States Claims Court ("court.")[10] The court would then analyze the situation and determine whether a patent had been used without the permission of the owner and further determine the *reasonable and entire* compensation to be awarded to the patent holder.

ANALYSIS

Since its enactment in 1910, section 1498 has been subject to extensive judicial scrutiny and review. Although it does not appear that there has been a case involving the government's "taking" of a pharmaceutical patent, various other cases involving the government's uses of patented processes and devices provide precedent and guidance for a judicial review of a pharmaceutical "taking." Initially, the Court of Claims and, after 1982, the Claims Court scrutinized various situations involving governmental use of patented processes and determined whether the federal government had indeed "taken" a patent. If a "taking" was determined to have occurred, the courts would calculate the plaintiff's "reasonable and entire" compensation for such a use or taking.

An analysis of several key cases involving claims brought concerning federal use of patented devices/processes provides insight into the judicial reasoning and determinations resulting in the award of damages to the patent

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[9] 28 U.S.C. § 1498(a)(1982).

[10] Prior to the 1982 amendments (Pub. L. 97-164, title I, § 133(d)(1), Apr. 2, 1982, 96 Stat. 40), remedies for the taking of private patent rights by the federal government were brought in the United States Court of Claims.

holder. Most of the cases present two questions: first, was there a government "taking or use" of the patent; and second, if so, what is the "reasonable and entire" compensation which the patent holder is entitled to by section 1498.[11]

Early cases considered the parameters of "reasonable and entire" compensation. In a 1931 case, the Supreme Court held that interest would be permitted when determining the extent of the damages assessed against the federal government.[12] In another early and important case, *Marconi Wireless Telegraph Company of America v. United States*, [13] the court devised a licensing or leasing approach in its determination of a suitable settlement to the patent holder. In resolving what was "reasonable and entire" compensation, the court undertook detailed and complex accounting procedures, as well as comparative market approaches. After an extensive examination of licensing procedures, the court determined that the patent holder was entitled to a 10% "licensing" fee-type compensation from the government. This royalty or licensing fee represented 10% of the selling price or market value of the actual patented products.[14] In the *Fauber* case,[15] the court adopted a similar accounting-type approach and also provided an interest payment for the patent holder. In this case, a 4% royalty was assessed on the market value of each manufactured product which was "taken" by the federal government. [16]

Later cases also adopted detailed accounting and investigative procedures in determining "reasonable and entire" compensation for the patent holder. Market conditions and comparative licensing arrangements were examined by the courts, as well as prevailing interest rates. In *Pitcairn*,[17] the court examined at great length the concept of a "taking" of a patented device by the

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[11] *See,* Lipscomb, *Lipscomb's Walker on Patents* § 22:22 (1987).

[12] *Waite v. United States*, 282 U.S. 508 (1931).

[13] 99 Ct.Cl. 1 (1942), *modified on other grounds*, 320 U.S. 1 (1943), *reh'g denied*, 320 U.S. 809 (1943).

[14] *Id.*, at 22. The court computed the entire market value of the patented apparatus and determined that the reasonable and entire compensation was 10% of the market value of the devices which were actually "taken" by the federal government. *Id.*

[15] *Fauber v. United States*, 81 F.Supp. 218 (Ct.Cl. 1948), *cert. denied*, 337 U.S. 906 (1949).

[16] *Id.*, at 219.

[17] *Pitcairn v. United States*, 547 F.2d 1106 (Ct.Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978).

government and characterized this taking as a license in the patent. The court also articulated the concept of "delay compensation," the payment to the patent holder for the wait or delay in receiving compensation.[18] The court adopted the willing buyer-willing seller approach in computing compensation in the *Tektronix* case.[19] In reaching its estimation of "reasonable and entire" compensation, the court tried to establish the marketplace within the context of its judicial determination. After its review of the "marketplace," the court based its 10% royalty on its best judgment of what reasonable parties might have agreed upon in the open market in a licensing arrangement. The court characterized a "reasonable royalty" as a "device in aid of justice," whereby something incalculable is approximated.[20]

Another case of considerable importance in the determination of damages under section 1498 actions was *Leesona Corp. v. United States*.[21] This case examined the damages which a plaintiff could secure against the United States. In this action, the damage award had initially been based upon a tort claim, rather than under the theory of eminent domain under section 1498.[22] It appears that recovery under section 1498 on the basis of a tort theory was unique and was ultimately rejected by the Court of Claims.[23] Research has not discovered any later cases basing an award upon the tort theory. Furthermore, the plaintiff sought multiple damages and attorney fees. The Court of Claims determined that a comparative royalty technique was the preferred method for determining just compensation.[24] "The proper measure in eminent domain is what the owner has lost, not what the taker has gained."[25] The court specifically rejected the concept of double damages, based

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[18] *Id.*, at 1120 *et. seq.*

[19] *Tektronix, Inc. v. United States*, 552 F.2d 343 (Ct.Cl. 1977), *reh'g denied*, 557 F.2d 265 (Ct.Cl. 1977).

[20] 552 F.2d 343, 351 (Ct.Cl. 1977).

[21] 599 F.2d 958 (Ct.Cl. 1979).

[22] In a prior action, *Leesona Corp. v. United States*, 530 F.2d 896 (Ct.Cl. 1976), the Court of Claims had held that three patents owned by Leesona were valid and had been infringed by the United States. The Court of Claims then referred the "accounting phase" of the action to Trial Judge Browne who based his damages upon a tort theory of recovery. 599 F.2d 958, 962 (Ct.Cl. 1979). The Court of Claims reconsidered the damages determined in the "accounting phase" and set aside the findings of Trial Judge Browne. *Id.*

[23] *Id.*, at 962.

[24] *Id.*, at 967 *et. seq.*

[25] *Id.*, at 969.

upon the government's alleged bad faith.[26] Another issue which *Leesona* clarified was the rejection of an additional damage award to the plaintiff based upon savings to the federal government through the use of plaintiff's patent.[27] However, the court held that savings to the government could be considered in the determination of "reasonable compensation."[28] Thus, this case set forth important principles in the determination of compensation: damages should be based upon an eminent domain theory rather than upon a tort claim; plaintiffs were not to be awarded multiple damages and attorney fees; and plaintiffs were not entitled to a special award based upon government savings, although such savings could be considered in the determination of reasonable compensation. Thus, *Leesona* set forth the principle that damages under section 1498 actions should be based upon the theory of eminent domain, rather than upon the basis of tort claims.

Applying the principles provided by *Leesona*, the court in *Bendix Corp. v. United States*[29] determined that the proper measure of damages was through a determination of damages based upon the theory of eminent domain.

> Because 28 U.S.C. § 1498 permits the government to take a license, through exercise of its eminent domain power, in any United States patent, we concluded that the government had taken a royalty-bearing license in plaintiff's patent.[30]

Based upon this concept, the court determined what would be a reasonable recovery based upon a royalty theory. The court also awarded delay compensation.[31]

In considering the possible recovery that a pharmaceutical patent plaintiff could receive, several principles can be gleaned from the above cases. First, the court must determine whether a "taking" of a patent has occurred. It appears likely from the hypothetical fact situation described in footnote one that the court would determine that a taking had occurred. The court's next task is to compute "reasonable and entire" compensation. In its computation of such compensation, the court would probably consider the government use under a theory of taking or eminent domain, rather than under a tort theory.

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[26] *Id.*

[27] *Id.*, at 971.

[28] *Id.*

[29] 676 F.2d 606 (Ct.Cl. 1982).

[30] *Id.*, at 607.

[31] *Id.*, at 615.

Under the eminent domain theory, the court would probably try to determine a licensing approach[32] to determine what sort of licensing fee the patent holder would have received on the open market. Although the plaintiff could not recover a specific award based upon the savings that the government may have received through the use of his/her patent, such savings would probably be considered in the basis for the licensing award. Upon the basis of *Leesona*, the court would probably not permit multiple or punitive damages and the plaintiff probably would not be eligible for the recovery of attorneys' fees and other expenses. Thus, the court would probably try to calculate a licensing fee based upon prevailing market conditions and base damages upon this licensing fee.[33] In addition, the court could also award delay compensation to the plaintiff.

CONCLUSION

Congress has provided a means to compensate patent holders whose patents have been "taken" by the federal government through section 1498. Such compensation is required by the statute to be "reasonable and entire." Through the years, courts have determined the meaning of this requirement in very specific situations. Numerous aspects of a case have been considered by the court in its attempt to award damages. Although it does not appear that there has been an action brought under the section for pharmaceutical use, existing case law provides guidance as to what courts might consider in such an action. Most likely, the court would approach the issue of damages through a licensing approach, rather than upon a tort theory. It is speculative to attempt to determine what a court would consider to be "reasonable and entire" compensation in a pharmaceutical case, but other taking cases in the patent area have set forth guidelines which establish possible parameters for the awarding of damages in the instant situation.

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Legislative Attorney

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[32] The court might base a licensing percentage upon the fair market price or value of the infringed products.

[33] See, Chisum, *Patents* § 1606[3](Vol. 4)(1988 Supp.)

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Procedure on claims for damages for unjust conviction and imprisonment, see section 2513 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 2513 of this title.

§ 1496. Disbursing officers' claims

The United States Claims Court shall have jurisdiction to render judgment upon any claim by a disbursing officer of the United States or by his administrator or executor for relief from responsibility for loss, in line of duty, of Government funds, vouchers, records or other papers in his charge.

(June 25, 1948, ch. 646, 62 Stat. 941; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(c)(1), 96 Stat. 40.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., § 250(3) (Mar. 3, 1911, ch. 231, § 145, 36 Stat. 1136; June 10, 1921, ch. 18, § 304, 42 Stat. 24).

Words "paymaster, quartermaster, commissary of subsistence, or other," preceding "disbursing officer of the United States," were omitted. See *Henderson* v. *United States*, 1907, 42 Ct.Cl. 449 and *Hobbs* v. *United States*, 1881, 17 Ct.Cl. 189, holding that the term "other disbursing officer" extends to any disbursing officer of the executive departments of the Government.

Words "by capture or otherwise" were omitted as surplusage.

Words "and for which such officer was and is held responsible," at the end of section 250(3) of title 28, U.S.C., 1940 ed., were omitted as surplusage.

Changes were made in phraseology.

AMENDMENTS

1982—Pub. L. 97-164 substituted "United States Claims Court" for "Court of Claims".

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Allowance of credit in settlement of disbursing officers' accounts, see section 2512 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in title 41 section 114.

§ 1497. Oyster growers' damages from dredging operations

The United States Claims Court shall have jurisdiction to render judgment upon any claim for damages to oyster growers on private or leased lands or bottoms arising from dredging operations or use of other machinery and equipment in making river and harbor improvements authorized by Act of Congress.

(June 25, 1948, ch. 646, 62 Stat. 941; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(c), 96 Stat. 40.)

HISTORICAL AND REVISION NOTES

Based on title 28, U.S.C., 1940 ed., § 250a (Aug. 30, 1935, ch. 831, § 13, 49 Stat. 1049; July 13, 1943, ch. 231, 57 Stat. 553).

The proviso at the end of section 250a of title 28, U.S.C., 1940 ed., is incorporated in section 2501 of this title.

Words "river and harbor improvements" were substituted for "such improvements", in view of Dixon v. U.S., 103 Ct. Cl. 160, holding that words, "such improvements" were not limited to the specific improvements listed in the 1935 act, but applied to any river and harbor improvements.

Changes were made in phraseology.

AMENDMENTS

1982—Pub. L. 97-164 substituted "growers'" for "growers," in the section catchline, and in text substituted "United States Claims Court" for "Court of Claims".

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97-164 effective Oct. 1, 1982, see section 402 of Pub. L. 97-164, set out as a note under section 171 of this title.

CROSS REFERENCES

Time for filing petition by oyster growers, see section 2501 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 2501 of this title.

§ 1498. Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Claims Court for the recovery of his reasonable and entire compensation for such use and manufacture.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which

Government time, materials or facilities were used.

(b) Hereafter, whenever the copyright in any work protected under the copyright laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government and with the authorization or consent of the Government, the exclusive remedy of the owner of such copyright shall be by action against the United States in the Claims Court for the recovery of his reasonable and entire compensation as damages for such infringement, including the minimum statutory damages as set forth in section 504(c) of title 17, United States Code: *Provided*, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the copyrighted work by the Government: *Provided, however*, That this subsection shall not confer a right of action on any copyright owner or any assignee of such owner with respect to any copyrighted work prepared by a person while in the employment or service of the United States, where the copyrighted work was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: *And provided further*, That before such action against the United States has been instituted the appropriate corporation owned or controlled by the United States or the head of the appropriate department or agency of the Government, as the case may be, is authorized to enter into an agreement with the copyright owner in full settlement and compromise for the damages accruing to him by reason of such infringement and to settle the claim administratively out of available appropriations.

Except as otherwise provided by law, no recovery shall be had for any infringement of a copyright covered by this subsection committed more than three years prior to the filing of the complaint or counterclaim for infringement in the action, except that the period between the date of receipt of a written claim for compensation by the Department or agency of the Government or corporation owned or controlled by the United States, as the case may be, having authority to settle such claim and the date of mailing by the Government of a notice to the claimant that his claim has been denied shall not be counted as a part of the three years, unless suit is brought before the last-mentioned date.

(c) The provisions of this section shall not apply to any claim arising in a foreign country.

(d) Hereafter, whenever a plant variety protected by a certificate of plant variety protection under the laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government, and with the authorization and consent of the Government, the exclusive remedy of the owner of such certificate shall be by action against the United States in the Claims Court for the recovery of his reasonable and entire compensation as damages for such infringement: *Provided*, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the protected plant variety by the Government: *Provided, however*, That this subsection shall not confer a right of action on any certificate owner or any assignee of such owner with respect to any protected plant variety made by a person while in the employment or service of the United States, where such variety was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: *And provided further*, That before such action against the United States has been instituted, the appropriate corporation owned or controlled by the United States or the head of the appropriate agency of the Government, as the case may be, is authorized to enter into an agreement with the certificate owner in full settlement and compromise, for the damages accrued to him by reason of such infringement and to settle the claim administratively out of available appropriations.

(June 25, 1948, ch. 646, 62 Stat. 941; May 24, 1949, ch. 139, § 87, 63 Stat. 102; Oct. 31, 1951, ch. 655, § 50(c), 65 Stat. 727; July 17, 1952, ch. 930, 66 Stat. 757; Sept. 8, 1960, Pub. L. 86-726, §§ 1, 4, 74 Stat. 855, 856; Dec. 24, 1970, Pub. L. 91-577, title III, § 143(d), 84 Stat. 1559; Oct. 19, 1976, Pub. L. 94-553, title I, § 105(c), 90 Stat. 2599; Apr. 2, 1982, Pub. L. 97-164, title I, § 133(d), 96 Stat. 40.)

Historical and Revision Notes

1948 Act

Based on section 68 of title 35, U.S.C., 1940 ed., Patents (June 25, 1910, ch. 423, 36 Stat. 851; July 1, 1918, ch. 114, 40 Stat. 705).

Provisions contained in the second proviso of section 68 of title 35, U.S.C., 1940 ed., relating to right of the United States to any general or special defense available to defendants in patent infringement suits were omitted as unnecessary. In the absence of statutory restriction, any defense available to a private party is equally available to the United States.

Changes in phraseology were made.

1949 Act

This amendment clarifies section 1498 of title 28, U.S.C., by restating its first paragraph to conform more closely with the original law.

References in Text

Hereafter, referred to in subsec. (b), probably means the date of enactment of Pub. L. 86-726, which was approved on Sept. 8, 1960.

The copyright laws of the United States, referred to in subsec. (b), are classified generally to Title 17, Copyrights.

Hereafter, referred to in subsec. (d), probably means after the date of enactment of Pub. L. 91-577, which was approved on Dec. 24, 1970.

Amendments

1982—Subsec. (a). Pub. L. 97-164, § 133(d)(1), substituted "United States Claims Court" for "Court of Claims".