

a 1995 hearing of the House Judiciary Committee, Subcommittee on Courts and Intellectual Property. The bill, H.R. 1127, was opposed by the Biotechnology Industry Organization, the Section of Intellectual Property Law of the American Bar Association, and the American Intellectual Property Law Association.

An amendment to bar the Patent and Trademark Office from spending its funds to issue such patents was adopted on the Commerce-State-Justice appropriations bill in the House on July 24, 1996. Joining those opposed to this amendment were the Intellectual Property Owners, the Pharmaceutical Research and Manufacturers of America, and Chairman Moorhead and Ranking Member Schroeder of the Subcommittee that conducted the earlier hearing.

### SUBSTANTIVE CONCERNS

*Administration Opposition:* The Commissioner of Patents and Trademarks, Bruce Lehman, testified before the Senate Judiciary Committee on September 18, 1996, and stated that the Administration opposes both the Ganske Amendment and the latest Ganske/Frist compromise. Commissioner Lehman noted that the area of medical technology is particularly patent-dependent and expressed his concern that we not overreact in a fashion that jeopardizes "the goose that lays the golden egg".

*Impact on Medical Research:* The supporters of the Ganske/Frist compromise can provide no assurance that enactment of this legislation would not impede timely future development of critical "pure" medical procedures. As Commissioner Lehman has testified, patents are often useful in attracting investment capital. It is impossible to state categorically today, as the Ganske/Frist legislation seems to presume, that tomorrow's advances in "pure" medical procedures will take place as expeditiously as possible absent patent protection. As Commissioner Lehman told the Judiciary Committee: "It would be really quite tragic if we were to find that a very large loophole were to be opened in the patent system that would cause investment in some of the most important technology—not just from an economic point of view but from a life-saving point of view, to cause that investment to dry up."

Biomedical researchers, physicians, and other health care professionals are to be saluted for their rich tradition of public disclosure and free exchange of ideas. That this long-standing iterative educational process often acts to preclude compliance with the strict legal requirements of the patent system does not necessarily lead to the conclusion that all medical processes should not be patentable. In no other field would one suggest that the incentives of the patent system be eliminated in the hope that technical progress would proceed unabated.

*Patent Protection Available to All:* For these reasons, the Administration is joined in opposing this legislation by the Section of Intellectual Property Law of the American Bar Association which believes the proposals:

"... violate a fundamental principle of our law under which patent protection is available without discrimination as to field of invention or technology. The Frist/Coalition approach is doubly discriminatory in that it would achieve this result by discriminatory treatment based on the identity or profession of the infringer. . . . The Section of Intellectual Property Law believes that it would be both unfair and counterproductive to single out one area of creativity—the creation of new and improved medical procedures—and deny rewards to those creators while providing them to all others."

*The Case for Changing the Law Has Not Been Made:* Section 101 of the patent code—which broadly defines the subject matter eligible for patenting—has been essentially unchanged for over 200 years. The Ganske/Frist initiative reverses this long history of statutory and case law and, without adequate justification, precludes the patenting of an extremely important field of endeavor—medical processes. The patent code should not be changed on the basis of anecdotal evidence.

It is particularly perplexing that in the case that precipitated the current controversy, the Pallin suture-less cataract operation, the system worked, and the patent has not been enforced by the courts.

Moreover, to the extent that the Ganske/Frist compromise is designed to reduce litigation costs, it is difficult to see how it accomplishes this goal. Where a medical process involves any type of instrument, a motion for summary judgment could likely involve contested issues of fact that would subject physicians to the expenses of litigation, even where they would ultimately not be subject to remedies.

*A Right Without a Remedy:* The latest Ganske/Frist compromise provides the right to patent medical procedure without a remedy against the most likely class of infringers (medical practitioners). This violates one of the most fundamental benefits of the United States patent system—the right to exclusive use. Severely limiting the remedies available under section 287 of the patent code is tantamount to amending what is patentable under the 200 year old language of section 101. A patent without a meaningful remedy against infringement is like no patent at all.

*Individual Inventors vs. Multi-Million Dollar Corporations:* By extending protection to organizations that employ physicians such as health maintenance organizations, the Ganske/Frist legislation raises equity questions concerning the proper balancing of rights of individual inventors versus large corporations. We must think carefully before we take away the rights of individual inventors by not allowing enforcement against patent infringement by multi-million dollar corporations.

*Trade Implications:* The House-passed Ganske amendment to limit the authority to expend funds to issue medical procedure patents undercuts the hard fought gains of the GATT Treaty TRIPS provisions (Trade-Related Intellectual Property Rights). The House language invites, however unintentionally, our trading partners to adopt intellectual property protections that comply with TRIPS but, at the same time, functionally nullifies these apparent gains by simply not appropriating administrative funds. If this technique were used by our foreign trading partners not to enforce American-owned patents on, for example, pharmaceuticals or automobile parts, Congress and the public would demand action.

*Not Reviewed by Finance Committee:* This latest Ganske/Frist compromise raises novel, complicated, and sensitive issues of far-ranging precedential significance relating to Articles 27, 28, and 30 of TRIPS. These issues need to be thoroughly examined and merit careful consideration and debate by the Judiciary Committee, the Finance Committee, and the full Senate. There is no consensus on these issues. We have not had an opportunity to hear from the United States Trade Representative or the Secretary of Commerce on these matters. For example, the American Intellectual Property Law Association has noted that this amendment:

"... would be very deleterious to the patent law and raises serious questions regarding the compliance by the United States with its obligations under TRIPS. This

amendment . . . should be rejected. The proponents have failed to demonstrate a need for this amendment. The amendment would proclaim an open season for exceptions to patent protection to address other alleged problems. Moreover, it would clearly be inimical to the interests of American industry for the United States to take the lead in weakening the patent protection required under Articles 28 and 30 of the TRIPS."

### OPPOSE THE GANSKE/FRIST AMENDMENT

*Oppose the Ganske/Frist Amendment:* In sum, the laws that allow the patenting of the broadest possible range of subject matter coupled with the three basic legal requirements of novelty, utility, and nonobviousness have proven effective over the long run. Our current statutory framework has met the Constitutional charge "to promote science and useful arts" and has helped make the United States the world's leader in medical technology. We should not change these laws absent a demonstration of a compelling need, and we should not use the omnibus appropriations vehicle for such a controversial change in substantive patent law.

Sincerely,

ORRIN G. HATCH,  
Chairman.

SEPTEMBER 27, 1996.

### SUBSTANTIAL OPPOSITION VOICED TO GANSKE/FRIST AMENDMENT

DEAR COLLEAGUE: In view of the upcoming debate on the omnibus appropriations bill, I thought you would want to be aware of several compelling arguments raised in opposition to proposed language barring medical procedure patents or their enforcement. I continue to oppose this proposal on both procedural and substantive grounds. Here's what some top intellectual property authorities are saying:

*The Clinton Administration:* The Clinton Administration opposes the Ganske/Frist amendment both as it passed the House and in its more recent version. In a July 17, 1996 letter to the House Appropriations Subcommittee, the Commerce Department stated,

"We continue to oppose enactment of H.R. 1127 (the Ganske bill) and any amendment that contains the substance of it. We still believe that it is premature to adopt such drastic steps when we have the opportunity to adopt administrative measures to mitigate the problem."

Moreover, in September 18, 1996 testimony before the Senate Judiciary Committee, PTO Commissioner Bruce Lehman expressed opposition to the latest compromise and the unprecedented loophole it would establish. PTO Commissioner Lehman said,

"I, personally, the Office, and the Administration are against the Ganske amendment, and we would be against a variation of that, too, and let me tell you why."

Commissioner Lehman's major points in opposition were:

This could be a case of overreaction to a specific circumstance. Even though that situation may be controversial, it is important not to kill the "goose that lays the golden egg," that is, the incentive for medical research;

There is no requirement that patent applications be filed. Historically, surgical procedures are not patented. When they are, it is usually because it is required as part of a business plan to attract the necessary capital for research and development;

We would not have the wonderful therapies we have right now in this country—we wouldn't have the medical and pharmaceutical industry that leads the world, that provides a level of health care second to none, if it weren't for the patent system. It

is one of the most patent-dependent industries that there is, and so we have to be extremely careful in tampering with that system.

PTO Commissioner Lehman concluded, "It would be really quite tragic if we were to find that a very large loophole were to be opened in the patent system that would cause investment in some of the most important technology—not from an economic point of view, but from a life-saving point of view—to cause that investment to dry up."

*ABA Section of Intellectual Property Law:* In the attached letter, the ABA's Intellectual Property Section strongly opposes the original Ganske and Frist bills (H.R. 1127/S. 1134), as well as the Ganske amendment adopted in the House as part of the Commerce Department appropriations bill and a more recent variation advanced by the Medical Procedures Patents Coalition. The ABA Intellectual Property Law Section says:

"All the proposals violate a fundamental principle of our law under which patent protection is available without discrimination as to field of invention of technology. The Frist/Coalition approach is doubly discriminatory in that it would achieve this result by discriminatory treatment based on the identity or profession of the infringer."

The Intellectual Property Law Section raises several concerns about the latest proposal, concerns which have not been examined by any committee of Congress. These concerns include: the negative impact on the America's world leadership in scientific and technological development by singling out one area of creativity and denying rewards to those creators while providing them to all others; the international impact of making this change to accommodate narrow domestic interests; and the unworkability and ineffectiveness of the proposals.

*The American Intellectual Property Law Association:* In a September 16, 1996, letter, the American Intellectual Property Law Association said,

"This amendment, which would limit the remedies available against physicians and health care organizations for infringing medical procedure patents, should be rejected. The proponents have failed to demonstrate a need for this amendment. The amendment would proclaim an open season for exceptions to patent protection to address other alleged problems.

"Moreover, it would clearly be inimical to the interests of American industry for the United States to take the lead in weakening the patent protection required under Articles 28 and 30 of TRIPs."

*The Intellectual Property Owners:* The Intellectual Property Owners' Association represents companies and inventors who own patents, copyrights and trademarks in all fields of endeavor. In a letter expressing strong opposition to the Ganske amendment, the IPO has said,

"The amendment will harm members of our association who are investing in medical research. Moreover, the amendment amounts to a full employment law for attorneys. Attorneys and the U.S. Patent and Trademark Office will spend huge amounts of money litigating the scope of the amendment, adding to the already too high cost of obtaining and enforcing patents."

Further, in a separate letter commenting on a more recent version of the amendment, the IPO says,

"The proposal made by the American Medical Association and pharmaceutical and biotechnology trade associations to limit remedies for patent infringement by physicians and medical organizations is a dangerous precedent. It could undercut the efforts of the United States to strengthen patent rights in countries throughout the world in

all fields of technology. We hope Congress will not rush to judgement with legislation that will cause expensive litigation or diminish the strong incentives that the United States has traditionally provided for medical research."

Accordingly, I urge you to join these leaders in the field of intellectual property in opposing inclusion of this unstudied proposal in the end-of-the-year appropriations bill.

Sincerely,

ORRIN G. HATCH,  
Chairman.

AMERICAN BAR ASSOCIATION,  
Chicago, IL, September 11, 1996.

Hon. ORRIN G. HATCH,  
Chairman, Committee on the Judiciary, United States Senate, Washington, DC.

DEAR MR. CHAIRMAN: I am writing to express the opposition of the Section of Intellectual Property Law of the American Bar Association to S. 1134, the "Medical Procedures Innovation and Affordability Act", and to a similar proposal recently advanced by the Medical Procedures Coalition (hereafter referred to as "the Coalition proposal"). These views have not been considered or approved by the House of Delegates or Board of Governors of the American Bar Association.

S. 1134 and the Coalition proposal are two of four proposals currently pending in Congress, or which Congress has been asked to consider, to curtail patent rights for medical and surgical procedures. H.R. 1127, the "Medical Procedures Innovation and Affordability Act," introduced in the House on March 3, 1995 by Mr. Ganske, would prohibit patenting of inventions relating to certain medical and surgical procedures. On July 24 of this year, an amendment by Mr. Ganske relating to these issues was adopted in the House during consideration of H.R. 3814, the FY97 Commerce, Justice, State Appropriations Act. The Ganske amendment would achieve a ban on patenting of medical procedures similar to that called for in H.R. 1127 by a restriction on use of appropriated funds. H.R. 3814, including the Ganske amendment, is pending in the Senate.

The Ganske bill and the Ganske amendment attempt to insulate medical practitioners from liability for infringement of patents on medical procedures by denying patent protection to such procedures. Senator Frist's bill, S. 1134, and the Coalition proposal attempt to achieve the same result by denying legal remedies to owners of patents on these procedures when their patents are infringed by medical practitioners. We oppose both approaches and we oppose all four proposals. All the proposals violate a fundamental principle of our law under which patent protection is available without discrimination as to field of invention or technology. The Frist/Coalition approach is doubly discriminatory in that it would achieve this result by discriminatory treatment based on the identity or profession of the infringer.

The Section of Intellectual Property Law believes that it would be both unfair and counterproductive to single out one area of creativity—the creation of new and improved medical procedures—and deny rewards to those creators while providing them to all others. Our world leadership in scientific and technological development, a leadership which most particularly includes leadership in development of improved medical technology and procedures, has been achieved in large part because of, not in spite of, the controls and rewards which our system gives to our innovators.

For decades the United States has urged all nations to adopt laws protecting intellectual property fully and without discrimination. These efforts have been largely success-

ful, but are by no means over. In the ongoing talks regarding a Diplomatic Conference on Certain Copyright and Neighboring Rights Questions, critical issues regarding legal protection for emerging new areas of innovations are being addressed. The United States would be sending a dangerous message to these efforts by carving out a glaring exception to our system of uniform protection in order to accommodate narrow domestic interests which can be addressed, and are already being addressed, with far less radical measures.

S. 1134 and the Coalition proposal are apparently designed to address earlier criticism of H.R. 1127. However, they attempt to fix a fundamentally unsound and conceptually flawed proposal by narrowing its exclusionary provisions so that patent protection is not denied in areas where that denial presents policy or political impediments to enactment of the legislation. We believe that our legal framework for the promotion and protection of intellectual creativity, the finest and most successful that the world has known, would not be strengthened by such short-sighted statutory gerrymandering.

We also believe that the proposals based on restrictions on remedies are unworkable and would not achieve the intended results. As we understand it, the objective of these proposals is to provide a legal framework in which to prevent successful lawsuits against medical practitioners for the practice of certain medical procedures. Ideally this would be achieved by such suits never being filed. However, since plaintiffs control the filing of lawsuits, a more realistic objective seems to be to provide for early identification and expedited procedures for the dismissal or other disposition of such cases. If such a "gatekeeper" system is not functioning, the legislation would be of little utility. For example, if lengthy and costly discovery proceedings are required or permitted before a case can be weeded out, the legislation will provide little if any relief of the nature sought by medical practitioners and their supporters. In fact, such legislation might very well increase litigation and litigation costs, through a combination of failure to reduce existing litigation and additional litigation over the meaning and effort of the legislation itself.

We believe these are precisely the results which would flow from the enactment of these proposals. In this regard, we note that the Coalition proposal provides a number of exceptions to the general rule that legal remedies are not available for infringement arising out of the performance of medical or surgical procedures by medical practitioners, as well as an even broader, over-arching exclusion of coverage of certain activities relating to commercial development and distribution and the provision of pharmacy or clinical laboratory services.

One key exception in the proposal, relating to patented use of a composition of matter, provides that the exception does not apply to such use unless the use "directly contribute(s) to achievement of the objective of the claimed method." This is clearly an issue which is fact bound to a high degree, and not one that is likely to be resolved at the pleadings or motion stages of litigation. Proponents of the Coalition proposal suggest that legislative history can be treated to establish legislative intent that these fact-intensive questions can be decided by motion to dismiss or summary judgment. However, legislative history accompanying amendments to title 35 are unlikely to be found to be controlling legislative intent regarding application of Rules of Civil Procedure which are unchanged by the legislation, particularly when the intent expressed is in conflict

with the express language of the Rules themselves. (The Coalition suggests that a motion for summary judgment under Rule 56 may prevail by showing by a "preponderance of evidence" that certain essential facts exist. However, Rule 56 states that such a motion may be rendered only if "there is no genuine issue as to any material fact").

We strongly urge you to oppose all four versions of this legislative proposal.

Sincerely,

JOHN R. KIRK, Jr.  
Chair.

SEPTEMBER 28, 1996.

DEAR COLLEAGUE: I am writing to urge you to reject the Frist/Ganske proposal that would effectively prohibit medical procedure patents.

If you were in a car crash and ended up in the emergency room would you care whether your life was saved with a drug, or with a medical device, or with a surgical procedure? No, all you would care about is that the your life was saved through the most appropriate, up-to-date medical technology.

Why, then, should we adopt the untested Frist/Ganske amendment and suddenly reverse 200 years of patent law by rendering patents on life-saving medical procedures meaningless? Do you really want to take the chance that your doctor or the emergency room will be stuck with yesterday's technology because we hastily amended the patent law today?

My good friend, Senator Frist, recently posed the question: "Should the Heimlich maneuver be patentable? Imagine someone collecting a dollar every time someone used this or any other 'pure' medical procedure!" The fact is that many people would pay a dollar rather than take the risk of choking to death before they could get to the hospital. If you had a choice between the Heimlich Maneuver and an emergency tracheotomy, which would you choose? And, given the costs of emergency room visits, I am sure that the insurance company would opt for the simple, cost-effective procedure.

But, of course, the Heimlich maneuver, like most medical procedures, is not patented. We owe a debt of gratitude to Dr. Heimlich and all the other pioneers in medicine and health care practitioners, including Senator Frist and Representative Ganske, who are primarily motivated not to make money, but to save lives. We should also salute the tradition in the medical sciences of sharing information and freely exchanging ideas concerning the latest advances in medicine.

There is often an iterative educational dialogue that takes place during the medical research process. These interactions can act to defeat patentability because the strict legal requirements of demonstrating novelty and nonobviousness can not be satisfied by incremental or publicly discussed scientific achievements.

For example, in his recent Roll Call article, Representative Ganske criticized a patent issued in the area of breast reconstructive surgery. If, as Dr. Ganske states, "[this particular type of] breast reconstructive surgery had been in widespread use for at least 15 years. . .", then this patent should not have been issued in the first place and will not withstand court challenge.

The case that has fueled the current debate involved a patent issued to Dr. Samuel Pallin for a "no-stitch" cataract procedure. In a suit to enforce this patent against another surgeon, Dr. Jack Singer, a consent decree invalidating the patent was sanctioned by a court on grounds that the technique was already in use. In other words, the result feared by Senator Frist and Representative Ganske did not occur; the procedure failed the test for patent protection.

Senator Frist contends that "health care costs would explode if doctors charged licensing fees for every new surgical or medical technique. . ." And, on the issue of finding ways to reduce health care costs, I appreciate and generally agree with my colleague's suggestions. But the facts of the *Pallin* case reveal that—even with the requested \$4 per operation fee—appreciable cost savings are achieved when it is taken into account that each stitch not needed saves an estimated \$17.

Senator Frist takes the position that the basic rationale behind the American patent system—the encouragement of innovation—"does not apply to innovations in pure medical and surgical procedures because such innovations will occur without the benefit of patent law."

Many leading experts in intellectual property law take exception with this viewpoint. For example, the Commissioner of Patents and Trademarks, Bruce Lehman, expressed the Clinton Administration's opposition to the Frist/Ganske amendment by cautioning Congress not to overreact to the controversial *Pallin* case. As Commissioner Lehman recently explained his reasoning to the Senate Judiciary Committee:

"Historically, in the area of surgical procedures, people oftentimes don't file patent applications. When people file for patents, it is usually because they have to file a patent in order to get the financing to make that technology a reality \* \* \*

"It would be really quite tragic if we were to find that a very large loophole were to be opened in the patent system that would cause investment in some of the most important technology—not from an economic point of view but from a life-saving point of view, to cause that investment to dry up."

In contrast to the view that "these innovations would occur anyway," consider the assessment made by William D. Noonan, M.D., J.D., concerning the importance of patent protection for attracting private investment into the research that resulted in the surrogate embryo transfer (SET) procedure:

"The research that developed the SET procedure was financed with \$500,000 of venture capital because the National Institutes of Health (NIH) would not fund the research. It seems unlikely that the inventor of the SET process would have gotten this private funding if the process was not patentable subject matter."<sup>1</sup>

Moreover, Dr. Noonan points out that, "it is a questionable generalization to condemn all the therapeutic procedure patents merely because \* \* \* [of the *Pallin* 'no stitch' suture patent]" and that "there are instances in which medical advances may not be made if patent protection for a therapeutic method is not available."

At this point in time, there are simply too many unanswered questions about the Frist/Ganske amendment to justify sweeping this provision into the "end-of-the-session" omnibus appropriations legislation. Among these questions are:

Since there is no purported "emergency" need for the legislation (e.g., the *Pallin* cataract patent has not been enforced), and there has never been a hearing or mark-up in either the House or Senate on the language of the Frist/Ganske amendment, would it not be prudent for the respective Judiciary Committees' of each chamber to consider this legislation?

Given the precedent setting nature of this legislation for U.S. trade policy, particularly with respect to the proper interpretation and

application of Articles 27, 28, and 30 of the GATT Treaty TRIPs provisions, would it not be preferable for the Senate Finance Committee and House Ways and Means Committee to examine this issue in close consultation with the United States Trade Representative?

In a September 27, 1996 letter, the Office of the United States Trade Representative stated, "USTR has serious concerns about the consistency of the provision with the TRIPs Agreement. Moreover, we believe that the proposal sets a damaging precedent that other TRIPs Members might apply to other technologies." Why should we act in such haste in a way that may run afoul of the TRIPs agreement, and provide a roadmap for our trading partners who may use this example to justify the creation of broad exceptions for other technologies?

How can we be certain that costly and risky research will continue on tomorrow's seminal "pure" medical procedures in the absence of patent protection?

Why should the incentives associated with the patent system for research into medical procedures be any less or different than the incentives for research into drugs and medical devices?

As overall federal budgetary pressures constrain the growth of NIH funding, is this the time to decrease private sector incentives to invest in certain types of biomedical research?

What policy objectives are advanced by the Frist/Ganske amendment that prefers the rights of large corporate entities, such as HMOs, over the interests of individual inventors?

What are the implications of the provisions of the Frist/Ganske amendment that nominally allow medical procedure patents but then do not permit these patents to be enforced against the most likely infringers?

Until we know more about the answers to these and other questions, and we are able to get the answers on the record for all senators to consider, I urge my colleagues to oppose inclusion of the Frist/Ganske amendment on medical procedure patents in the omnibus appropriations bill.

Sincerely,

ORRIN G. HATCH,  
Chairman.

SEPTEMBER 18, 1996.

Hon. JUDD GREGG,  
Chairman, Subcommittee on Commerce, Justice,  
State and Judiciary, U.S. Senate, Washington, DC.

DEAR JUDD: I have significant concern about an amendment which was adopted during House consideration of H.R. 3418, the House Commerce, Justice, State appropriations bill. That amendment, authored by Rep. Greg Ganske, would limit the use of funds to approve patents for surgical or medical procedures or diagnoses. I want to express my appreciation to you and your staff for your efforts to defer consideration of this contentious issue pending review by the Judiciary Committee.

I understand the concerns which motivate the amendment and I am sympathetic to the issues which have been raised. However, I believe myriad questions can be raised about this proposal and its impact. The effect of this amendment would be to bar process patents for a certain industry, an exception never before made to our 200-year old patent law. A more recent version of the bill would allow the patents, but bar enforcement rendering the patent but an empty shell. Both of these would create tremendous precedents in patent law, precedents which are not supported by the intellectual property community. At a Judiciary Committee hearing today, Patent Commissioner Bruce Lehman

<sup>1</sup>William D. Noonan, M.D., J.D., "Patenting of Medical and Surgical Procedures," *Journal of the Patent and Trademark Office Society*, August, 1995, at 656-57.

also indicated that the Administration could not support either the Ganske provision or the recent variation.

In sum, I think that this issue needs to be more fully considered by the Congress, and in particular, by the Senate Judiciary Committee. I believe that passage of the Ganske provision, or the recent Frist modification, without adequate consideration of its long-term implications for intellectual property rights would be extremely unwise.

Let me hasten to add that I understand your special interest in this issue, and I am sympathetic to the need to examine further the impact of medical process patents. My study of the Singer case, in which the patent was overturned, leads me to believe that the Patent and Trademark Office's procedures could be improved in the area of medical patents. This is something that I will be pursuing, and I welcome your input into this process.

Sincerely,

ORRIN G. HATCH,  
Chairman.

Mr. HATCH. Mr. President, in closing, I must reiterate my profound disappointment and my objections to including this medical process patents provision in the omnibus appropriations bill. This is a serious matter and a serious precedent. We will have to look very carefully at its implications in the months to come.

#### ALTERNATIVE MEANS OF DISPUTE RESOLUTION ACT OF 1996

Mr. GRASSLEY. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 4194 which was received from the House.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

A bill (H.R. 4194) to reauthorize alternative means of dispute resolution in the Federal administrative process, and for other purposes.

The PRESIDING OFFICER. Is there objection to the immediate consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

AMENDMENT NO. 5421

(Purpose: To make amendment and to establish concurrent jurisdiction for purposes of hearing bid protests between the district courts of the United States and the United States Court of Federal claims and sunset bid protest jurisdiction of the district courts of the United States and other purposes)

Mr. GRASSLEY. Senator COHEN has an amendment at the desk and I ask for its immediate consideration.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Iowa [Mr. GRASSLEY], for Mr. COHEN, proposes an amendment numbered 5421.

Mr. GRASSLEY. I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

At the end of the bill insert the following:

#### SEC. 12. JURISDICTION OF THE UNITED STATES COURT OF FEDERAL CLAIMS AND THE DISTRICT COURTS OF THE UNITED STATES: BID PROTESTS.

(a) BID PROTESTS.—Section 1491 of Title 28, United States Code, is amended—

(1) by redesignating subsection (b) as subsection (c);

(2) in subsection (a) by striking out paragraph (3); and

(3) by inserting after subsection (a), the following new subsection:

“(b) (1) Both the United States Court of Federal Claims and the district courts of the United States shall have jurisdiction to render judgment on an action by an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement. Both the United States Court of Federal Claims and the district courts of the United States shall have jurisdiction to entertain such an action without regard to whether suit is instituted before or after the contract is awarded.

“(2) To afford relief in such an action, the courts may award any relief that the court considers proper, including declaratory and injunctive relief except that any monetary relief shall be limited to bid preparation and proposal costs.

“(3) In exercising jurisdiction under this subsection, the courts shall give due regard to the interests of national defense and national security and the need for expeditious resolution of the action.

“(4) In any action under this subsection, the courts shall review the agency's decision pursuant to the standards set forth in section 706 of title 5.”

(b) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect on December 31, 1996 and shall apply to all actions filed on or after that date.

(c) STUDY.—No earlier than 2 years after the effective date of this section, the United States General Accounting Office shall undertake a study regarding the concurrent jurisdiction of the district courts of the United States and the Court of Federal Claims over bid protests to determine whether concurrent jurisdiction is necessary. Such a study shall be completed no later than December 31, 1999, and shall specifically consider the effect of any proposed change on the ability of small businesses to challenge violations of federal procurement law.

(d) SUNSET.—The jurisdiction of the district courts of the United States over the actions described in section 1491(b)(1) of title 28, United States Code, (as amended by subsection (a) of this section) shall terminate on January 1, 2001 unless extended by Congress. The savings provisions in subsection (e) shall apply if the bid protest jurisdiction of the district courts of the United States terminates under this subsection.

(e) SAVINGS PROVISIONS.—

(1) ORDERS.—A termination under subsection (d) shall not terminate the effectiveness of orders that have been issued by a court in connection with an action within the jurisdiction of that court on or before December 31, 2000. Such orders shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked by a court of competent jurisdiction or by operation of law.

(2) PROCEEDINGS AND APPLICATIONS.—(A) A termination under subsection (d) shall not affect the jurisdiction of a court of the United States to continue with any proceeding that is pending before the court on December 31, 2000.

(B) Orders may be issued in any such proceeding, appeals may be taken therefrom, and payments may be made pursuant to such orders, as if such termination had not occurred. An order issued in any such proceeding shall continue in effect until modified, terminated, superseded, set aside, or revoked by a court of competent jurisdiction or by operation of law.

(C) Nothing in this paragraph prohibits the discontinuance or modification of any such proceeding under the same terms and conditions and to the same extent that proceeding could have been discontinued or modified absent such termination.

“(f) NONEXCLUSIVITY OF GAO REMEDIES.—In the event that the bid protest jurisdiction of the district courts of the United States is terminated pursuant to subsection (d), then section 3556 of title 31, United States Code, shall be amended by striking “a court of the United States or” in the first sentence.

Mr. COHEN. Mr. President, the amendment I am offering this morning to H.R. 4194, a bill to reauthorize alternative means of dispute resolution in the Federal administrative process, is the result of a compromise reached last night with the other house.

The amendment deals with the issue of bid protest jurisdiction in the Federal district courts and the U.S. Court of Federal Claims. The amendment will expand the bid protest jurisdiction of the Court of Federal Claims. It should be noted, however, that this amendment in no way expands the jurisdiction of the Court of Federal Claims beyond bid protests or changes the standard of review in any other area of jurisdiction of the Court of Federal Claims.

Currently, the Court of Federal Claims only has jurisdiction over bid protests which are filed before a contract award is made. My amendment provides for both pre- and post-award jurisdiction. The Federal district courts also have jurisdiction over bid protests. Prior to a 1969 Federal court decision, however, the Federal district courts had no jurisdiction over Federal contract awards. A Federal district court, in *Scanwell Lab., Inc. versus Shaffer*, held that a contractor can challenge a Federal contract award in Federal district court under the Administrative Procedures Act.

It is my belief that having multiple judicial bodies review bid protests of Federal contracts has resulted in forum shopping as litigants search for the most favorable forum. Additionally, the resulting disparate bodies of law between the circuits has created a situation where there is no national uniformity in resolving these disputes. That is why I have included provisions in this amendment for studying the issue of concurrent jurisdiction and have provided for the repeal of the Federal district courts' *Scanwell* jurisdiction after the study is complete in 2001.

The chamber of commerce fully supports this language as do our colleagues in the other chamber.

I would like to express my deep gratitude for the willingness of my colleagues and their staffs in both houses to work with me and my staff to develop this compromise.