501 "I Built that Mousetrap"—Responding to Letters Alleging Patent Infringement

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Faculty Biographies

Christopher J. Borders

Christopher J. Borders is the general counsel of MobShop, Inc., in San Francisco. MobShop, a venture-backed start-up company, licenses proprietary demand aggregation to online marketplaces and exchanges. He is responsible for all legal functions, including management of the company's portfolio of pending and issued patents and trademarks.

Prior to joining MobShop, Mr. Borders was a business and litigation partner in the Northern California office of Rivkin, Radler & Kremer, a New York-based general practice law firm. While at Rivkin, Radler, he represented internet and startup companies including InfoSeek/Go.com, AllBusiness.com, HomeGain.com, and Ofoto.com, as well as media and advertising agencies.

Mr. Borders currently serves on ACCA's Intellectual Property Committee's Executive Council and is a member of the Business Section of the State Bar of California. He also holds leadership positions in several youth soccer organizations and is a licensed soccer referee.

Mr. Borders received his BA from the University of California, Berkeley, and his JD from the University of California, Davis, M. L. King School of Law.

Michael P. Brennan

Michael P. Brennan is a managing principal and member of the executive committee of the law firm of Harness, Dickey & Pierce, PLC, one of the nation's oldest and best-known firms specializing in intellectual property. He joined the firm's litigation group 15 years ago. From 1984 until 1997, Mr. Brennan's practice was limited to conducting and managing IP and product liability litigation, as both first and second chair. Since 1997, Mr. Brennan's practice has been split evenly between IP litigation (and itsassociated risk management) and the creation of intellectual capital strategies. Mr. Brennan has written and lectured extensively on the subject of preserving the attorney-client privilege and work product immunity associated with freedom-to-practice opinions in IP litigation.

Mr. Brennan began his IP career with Procter & Gamble's Office of the General Counsel. His responsibilities included both the preparation of freedom-to-practice opinions and supervision of outside counsel's preparation of such opinions.

Mr. Brennan serves as an officer and director of the Intellectual Property Law Institute, a consortium of law schools dedicated to improving IP education.

He received a BS *cum laude* and JD *magna cum laude*.

Scott J. Coonan

Scott J. Coonan is currently employed as senior intellectual property attorney with the Hewlett-Packard Company (HP) in Cupertino, CA, where his clients include HP's consumer PC, online shopping, consulting services, and elearning businesses, among others. For those clients, Mr. Coonan prepares and negotiates a variety of agreements related to the creation, ownership, and licensing of technology; manages all patent prosecution activities; and handles intellectual property litigation matters.

Prior to joining HP, Mr. Coonan was intellectual property law counsel for Litton Industries, Inc., having responsibility for all intellectual property matters for eight division clients. Mr. Coonan began his legal career as a patent attorney for the intellectual property law firm of Killworth, Gottman, Hagan & Schaeff in Dayton, Ohio, after which he accepted a clerkship with a federal judge in Norfolk, Virginia. Before attending law school, he served for four years in the U.S. Air Force as an Acquisition Project Officer, attaining the rank of Captain.

Mr. Coonan is a member of ACCA's San Francisco Bay Area Chapter, the American Intellectual Property Law Association (AIPLA), and the Licensing Executives Society, Committee on Intellectual Capital Management.

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Carl J. Roof

Carl J. Roof is associate general counsel for The Procter & Gamble Company(P&G) in Cincinnati, Ohio. He has responsibility for global management of the patent and trade secret assets of P&G's Food & Beverage business unit.

Mr. Roof started his legal career with P&G as an intern 10 years ago and as a full time employee soon after. During the past nine years, he has supported P&G's pharmaceuticals, corporate research, beauty care, paper, corporate new ventures, and food and beverage businesses. Prior to attending law school, Mr. Roof was employed as a research scientist in P&G's Pharmaceuticals R&D organization.

Mr. Roof is a member of the Cincinnati Intellectual Property Law Association and the Cincinnati Bar Association.

Mr. Roof received his bachelor's degree from Ithaca College and his JD from Syracuse University College of Law.

SESSION 501: RESPONDING TO LETTERS ALLEGING PATENT INFRINGEMENT

SOME PRACTICAL ADVICE FOR MANAGING THE RISKS ASSOCIATED WITH PATENT INFRINGEMENT ACTIONS

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INTRODUCTION

When an allegation of patent infringement is directed to you by anyone, in any form, your response must address a number of objectives simultaneously. These should include:

1. Identifying and minimizing the risk of actual damages.
2. Identifying and minimizing the risk of temporary and/or permanent injunctive relief.
3. **Identifying and minimizing the risk of increased (treble) damages.**

   The most common way that a serious risk is brought to light is through the receipt of a formal "notice" letter from the patent owner/licensee or its counsel. Making certain that your response to the notice is both complete and appropriate is critical in managing the risks associated with nos. 2 and 3, above.

I. WHAT CONSTITUTES SUFFICIENT NOTICE TO CREATE EXPOSURE TO (INCREASED) DAMAGES?

A. There is no single test or standard. (See 35 U.S.C. § 287(a).)

B. Typically, the notice must identify the patent number and the allegedly infringing activity or product.

C. The "notice," oddly enough, does not need to be sufficient to meet the declaratory judgment standard (28 U.S.C. § 2201) – but sufficient notice usually will.

II. DOES YOUR ORGANIZATION HAVE SUFFICIENT SENSITIVITY TO IDENTIFY "NOTICES" AND GET THEM TO THE RIGHT PEOPLE?

When the notice is subtle or indirect, will it still get passed along? (Sales Staff: "Customer Q told us that our competitor, Bad Guys, Inc., thinks our product infringes its patent.") Forewarned is forearmed.

III. WHAT CAN YOU LEARN FROM THE TYPE OF NOTICE WHICH WILL HELP YOU ASSESS THE RISK AND FORMULATE AN APPROPRIATE RESPONSE?

A. Whom did it come from? The patent owner? The owner's exclusive licensee? A contingency fee firm? Indirectly – e.g., via a customer or vendor?

B. Does it signal that a request for preliminary relief will follow?

C. Is there an offer to license? (If so, the patentee is less likely to prevail in a motion for preliminary injunctive relief.)

D. Is it a subtle solicitation for *quid pro quo*? Does it seek a license under your IP?

E. Is it an unequivocal "get out of the market, or else!"?

F. Does it suggest there are "indirect" activities at risk (35 U.S.C. § 271(b), (c))?

IV. WHAT IS AN APPROPRIATE FORMAL RESPONSE?

A. This will clearly depend upon whether "notice" is a naked offer of a license; an offer of a license plus an allegation of infringement; or a direct, unambiguous charge of infringement.

B. Don't ignore a clear, direct charge of infringement or requested response deadline; these things typically don't go away.

C. Promptly acknowledge receipt of the correspondence, explain that meaningful investigation will take a certain amount of time, and be sure to follow up in the time you requested, or at least keep the other side updated on the status of your investigation. Remember, your overall goal is to be able to demonstrate, at trial, prudence and "good faith" in response to the notice!

D. Don't be shy about asking for detailed information underlying the threat.

E. If it is truly just an offer of a license, determine whether it can, nevertheless, be construed as notice?

F. A thoughtful and complete response is usually warranted; remember, however, that persuasion by mail is not a realistic objective.

V. WHAT IS APPROPRIATE INTERNAL RESPONSE?

A. Again, keep in mind that your real goal is to demonstrate that you acted with prudence and in "good faith" under the "totality of the circumstances" to avoid an increase in damages.

B. If notice is sufficient under § 287(a), opinion of counsel is the most common way of attempting to minimize increased damages. However, an opinion is only part of a typical "good faith" demonstration. It is not always necessary; it is not always dispositive of the "good faith" issue. (See discussion in Section VII, below.)

C. Don't overlook the obvious alternatives to spending money on a legal investigation and opinion. Modifying the product or taking a license may cost less than an opinion followed by litigation. Taking a license and then modifying the product to reduce future royalties is always worth considering.

D. Don't overlook the "not-so-obvious," such as buying the patent, buying the entity that owns the patent, or buying an entity that owns a license under the patent.

E. Examine your own IP portfolio to see if the patent owner/licensee is violating any of your IP rights (not just patent rights). Do you have something to trade?

F. Investigate the patent owner and its counsel thoroughly.

G. Make a preliminary inquiry as to the status of the patent – has it been properly assigned or licensed to the entity asserting the patent; have all maintenance fees been paid, or has the patent lapsed?

H. Try to solicit a willingness to license the patent if the notice doesn't clearly suggest such a willingness. This will reduce the likelihood of preliminary relief later.

I. Don't fall into the trap of concluding "it's only a design patent." (See the discussion on design patent remedies below.)

J. If the notice is formal and clear, it needs to be handled urgently!

K. Investigate whether the risk is insured or shared. Should you notify your carrier? Is there a vendor, supplier, or other "partner" that has contractually or statutorily assumed part or all of the exposure. (Note that the U.C.C. contains certain indemnification provisions for the sale of goods.) Notify these parties immediately.

DAMAGES SUMMARY

VI. DAMAGES AND OTHER REMEDIES – WHY ALL THE FUSS?

A. Injunctive Relief

While preliminary relief is granted with the same lack of predictability as in any civil action, permanent injunctions are ROUTINE (bordering on automatic) when there is a final determination of infringement at trial. 35 U.S.C. § 283.

B. Patent Infringement Damages

1. 35 U.S.C. § 284 has been the controlling damages statute for utility patent infringement since 1952. It states, in part:

"Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no

event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."

2. It is important to understand that there is only one legal measure for damages for patent infringement: an amount "adequate to compensate for the infringement."

3. 35 U.S.C. § 284 establishes a floor for damages at a reasonable royalty. THERE IS NO CEILING!!

4. It shouldn't be surprising that, given this latitude, there is no formula for calculating damages in a patent infringement case. The only limitation is the creativity of the claimant's counsel and experts. (Section 284 expressly permits expert testimony on the subject of patent damages.)

5. Rather than seeking the infringer's profits, it is common for a claimant to seek its lost profits (past and future) as an alternative to a reasonable royalty. This often allows the patent owner to recover significantly more than a reasonable royalty. The number of awards and settlements in excess of $100,000,000 is staggering.

6. It is also not uncommon for the patentee to seek significant damages, in addition to its lost profits. These typically include:

   (i) lost profits on unpatented items the patentee would have sold with the patented item;

   (ii) profit erosion on the depressed selling price of the patented product caused by the infringer (past and future);

(iii) a reasonable royalty on any product that doesn't qualify (legally) for lost profits;

(iv) prejudgment interest;

(v) postjudgment interest;

(vi) costs;

(vii) attorney fees; and

(viii) enhanced damages (up to three (3) times (i) - (iii) above) for failure of the infringer to act prudently and in good faith in the face of the patent.

7. Design patent owners have all the remedies available for utility patents under 35 U.S.C. §§ 284 and 285. Design patent holders also have a significant alternate remedy under 35 U.S.C. § 289. This additional remedy is not the right to collect damages, but to collect the infringer's profits. Typically, the patentee simply proves the infringer's gross sales; the infringer has the burden of showing the costs associated with the manufacture and sale of the product that should be deducted. Design patents, therefore, should not receive any less attention than utility patents.

8. There are a host of traps to be avoided and myths to be ignored in connection with patent litigation. Making assumptions based upon intuition, or extrapolating from other areas of the law, is extremely dangerous!! Seek experienced counsel.

MORE PRACTICAL ADVICE

VII. MANAGING THE RISKS ASSOCIATED WITH INCREASED DAMAGES

As a substantial deterrent to patent infringement, Congress has given the courts the authority to increase damage awards – awards that are already staggering. 35 U.S.C. § 284. If the court finds fault with the defendant-infringer's conduct, it can increase the basic award by any multiplier, up to three. It is essential that a party accused of infringement conduct itself in a way that will minimize the risk that a court would find an infringement to be "willful."

A. GUIDING PRINCIPALS

1. There are no rules as to what constitutes "willful" patent infringement. Nevertheless, it is an issue that has been much litigated, and a substantial body of case law has developed that now guides the courts.

2. The most commonly articulated test is whether the defendant acted with "reasonableness" and "prudence" under the totality of the circumstances. (For general guidance, please see *Underwater Devices, Inc. v. Morrison-Knudsen Co., Inc.*, 717 F.2d 1380 (Fed. Cir. 1983); *Central Soya Co., Inc. v. Geo. A. Hormel & Co.*, 723 F.2d 1573 (Fed. Cir. 1983); *Bott v. Four Star Corp.*, 807 F.2d 1567 (Fed. Cir. 1986); and *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 1428 (Fed. Cir. 1988).)

3. In short, did you act in the belief that you were not violating a valid and enforceable patent claim or claims?

4. By far, the most common "defense" to an allegation of willfulness is that the alleged infringer secured opinion of counsel on the infringement, validity, and/or enforceability of the patent(s) at issue.

5. An opinion is certainly valuable, and sometimes dispositive of the issue of willfulness. However, it is not always so. There are at least 15 decisions of the Court of Appeals for the Federal Court upholding a finding of willfulness in the face of an opinion-of-counsel "defense."

REMEMBER: In order to defend the allegation, all activities will likely be discoverable, including all conduct associated with obtaining opinion of counsel – AND SO WILL THE OPINION ITSELF! There may also be a waiver of the associated work product immunity. You should also assume that all counsel connected with the opinion will be deposed.

B. How Do I Minimize My Risk?

1. Get an opinion!

2. Get an opinion ***that is likely to be determined to be competent***!

a. The opinion should be from a patent attorney, not general counsel or a nonlawyer.

b. The opinion must be objective. Outside counsel is sometimes considered to be more objective than in-house counsel.

c. The opinion must be based on both adequate and accurate factual foundations. There should be full disclosure from the client.

d. The opinion should be in writing.

e. The opinion should discuss all relevant case law and the standards that apply.

f. The opinion should include a discussion of the important features of the relevant product or activity, the claims, and the file history.

g. The opinion should include a discussion of the Doctrine of Equivalents (if it includes a conclusion of noninfringement).

3. Get an opinion – even if your infringing activities began prior to becoming aware of the patent.

4. Get an opinion – even if your infringing activities began before the patent issued. You are not relieved of your duty to act reasonably just because your activities were unquestionably innocent at the start.

5. Make sure you agree with counsel's factual conclusions. Don't ignore facts that potentially conflict with or dilute those in the opinion. You will have difficulty claiming good-faith reliance upon an opinion you knew to be factually incorrect or incomplete. Also, be careful about "negotiating" the opinion.

6. FOLLOW THE ADVICE IN THE OPINION.

7. FOLLOW THE ADVICE IN THE OPINION.

ATTACHMENT A

SELECTED STATUTES FROM TITLE 35

§ 281. Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement, or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent, the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Claims Court, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice, proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure--

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

§ 283. Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

§ 284. Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

§ 285. Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

§ 286. Time limitation on damages

Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.

In the case of claims against the United States Government for use of a patented invention, the period before bringing suit, up to six years, between the date of receipt of a written claim for compensation by the department or agency of the Government 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 part of the period referred to in the preceding paragraph.

§ 287. Limitation on damages and other remedies; marking and notice

(a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 9006 of the Process Patent Amendments Act of 1988. The modifications of remedies provided in this subsection shall not be available to any person who –

(A) practiced the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, offer for sale, or sale of which constitutes the infringement.

(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product. The person subject to liability shall bear the burden of proving any such possession or transit.

(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider –

(i) the good faith demonstrated by the defendant with respect to a request for disclosure,

(ii) the good faith demonstrated by the plaintiff with respect to a request for disclosure, and

(iii) the need to restore the exclusive rights secured by the patent.

(B) For purposes of subparagraph (A), the following are evidence of good faith:

(i) a request for disclosure made by the defendant;

(ii) a response within a reasonable time by the person receiving the request for disclosure; and

(iii) the submission of the response by the defendant to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the defendant, together with a request for a written statement that the process claimed in any patent disclosed in the response is not used to produce such product.

The failure to perform any acts described in the preceding sentence is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances include the case in which, due to the nature of the product, the number of sources for the product, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid

infringement.

(4)(A) For purposes of this subsection, a "request for disclosure" means a written request made to a person then engaged in the manufacture of a product to identify all process patents owned by or licensed to that person, as of the time of the request, that the person then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold, offered for sale, or used in, the United States by an unauthorized person. A request for disclosure is further limited to a request –

(i) which is made by a person regularly engaged in the United States in the sale of the same type of products as those manufactured by the person to whom the request is directed, or which includes facts showing that the person making the request plans to engage in the sale of such products in the United States;

(ii) which is made by such person before the person's first importation, use, offer for sale, or sale of units of the product produced by an infringing process and before the person had notice of infringement with respect to the product; and

(iii) which includes a representation by the person making the request that such person will promptly submit the patents identified pursuant to the request to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the person making the request, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

(B) In the case of a request for disclosure received by a person to whom a patent is licensed, that person shall either identify the patent or promptly notify the licensor of the request for disclosure.

(C) A person who has marked, in the manner prescribed by subsection (a), the number of the process patent on all products made by the patented process which have been offered for sale or sold by that person in the United States, or imported by the person into the United States, before a request for disclosure is received is not required to respond to the request for disclosure. For purposes of the preceding sentence, the term "all products" does not include products made before the effective date of the Process Patent Amendments Act of 1988.

(5)(A) For purposes of this subsection, notice of infringement means actual knowledge, or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a process patented in the United States.

(B) A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder's belief, except that the patent holder is not required to disclose any trade secret information.

(C) A person who receives a written notification described in subparagraph (B) or a written response to a request for disclosure described in paragraph (4) shall be deemed to have notice of infringement with respect to any patent referred to in such written notification or response unless that person, absent mitigating circumstances –

(i) promptly transmits the written notification or response to the manufacturer or, if the manufacturer is not known, to the supplier, of the product purchased or to be purchased by that person; and

(ii) receives a written statement from the manufacturer or supplier which on its

face sets forth a well grounded factual basis for a belief that the identified patents are not infringed.

(D) For purposes of this subsection, a person who obtains a product made by a process patented in the United States in a quantity which is abnormally large in relation to the volume of business of such person or an efficient inventory level shall be rebuttably presumed to have actual knowledge that the product was made by such patented process.

(6) A person who receives a response to a request for disclosure under this subsection shall pay to the person to whom the request was made a reasonable fee to cover actual costs incurred in complying with the request, which may not exceed the cost of a commercially available automated patent search of the matter involved, but in no case more than $500.

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

(B) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term "professional affiliation" shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.

(E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

(G) the term "State" shall mean any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or

distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(4) This subsection shall not apply to any patent issued based on an application the earliest effective filing date of which is prior to September 30, 1996.

