



Vidas, Arrett & Steinkraus, P.A.

Major expansion of the prior commercial use defense - we advise clients to keep detailed internal records of their commercial development and use of their inventions 35 USC §273

Executive Summary

The “prior commercial use” defense to infringement, previously limited to business methods, has been dramatically expanded to include “subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process may now serve as a defense to infringement.”

This defense is limited to prior use in the US and applies to any patent issued on or after September 16, 2011. It is also limited to sites where the prior use occurred.

We advise clients to keep detailed internal records of their commercial development and use of their inventions. If you have any questions concerning how this change impacts you or if you would like help setting up a record keeping protocol to document your prior internal use, please contact us.

If your client is facing litigation US and has secret prior use of the subject matter in the US, contact us so that we can determine if a prior use defense is available.

Detailed Discussion

Under the terms of the America Invents Act (AIA), the prior commercial use defense is no longer limited to business methods patents. The expanded prior art defense applies to prior commercial use of subject matter consisting of a process, or consisting of a machine, manufacture, or composition of matter used in a manufacturing or other commercial process

The expanded defense applies to all patents issued on or after September 16, 2011.

To qualify for the defense, the prior use had to have been:

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1) in the US in connection with an internal commercial use or an actual arm's length sale or other arm's length commercial transfer of a useful end result of such commercial use; and

2) at least 1 year before the earlier of either of:

(A) the effective filing date of the claimed invention;

or

(B) the date on which the claimed invention was disclosed to the public in a manner that qualified for the exception from prior art under section 102(b).

The person asserting the defense has the burden of establishing the defense by clear and convincing evidence.

Commercial use includes subjecting a device to a required US premarketing regulatory review. Also, use of the subject matter by a nonprofit research laboratory/other nonprofit entity, such as a university or hospital, for which the public is the intended beneficiary, is considered to be a commercial use to the extent that the use is continued and noncommercial.

The sale or other disposition of a useful end result by a person entitled to assert defense exhausts a patent owner's rights under the patent to the extent that such rights would have been exhausted had such sale or other disposition been made by the patent owner.

Limitation of the defense

1) The defense is limited to a person who performed/directed the performance of the commercial use or by an entity that controls, is controlled by, or is under common control with such person.

2) The right to assert a defense under this section cannot not be licensed or assigned or transferred (except to the patent holder) except as part of a good-faith assignment or transfer for other reasons of the entire enterprise or line of business to which the defense relates.

3) The defense is limited as to uses at sites where the subject matter that would otherwise infringe a claimed invention is in use before the later of the effective filing date of the claimed invention or the date of the assignment or transfer of such enterprise or line of business.

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4) The defense cannot be asserted if the subject matter was derived from patentee or persons in privity with patentee.

5) The defense is not a general license under all claims of the patent at issue. It is limited to subject matter for which it has been established that a commercial use that qualifies occurred.

6) The defense extends to variations in the quantity or volume of use of the claimed subject matter.

7) The defense extends to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

8) A person who has abandoned commercial use of subject matter may not rely on activities performed before the date of such abandonment in establishing a defense.

9) **UNIVERSITY EXCEPTION** – The defense does not apply if claimed invention was, at the time the invention was made, owned or subject to an obligation of assignment to either an institution of higher education or a technology transfer organization whose primary purpose is to facilitate the commercialization of technologies developed by one or more such institutions of higher education.

10) **Exception to University Exception** – The University Exception does not apply if any of the activities required to reduce to practice the subject matter of the claimed invention could not have been undertaken using funds provided by the Federal Government. Example: stem cell research.

If no reasonable basis for asserting defense, the defendant could be subject to damages as a willful infringer in the event that the defendant is determined to have infringed the patent.

Finally, a patent shall not be deemed to be invalid under section 102 or 103 solely because a defense is raised or established under this section.