

18 Court Decisions Related to the Experimental Use Exception under Common Law and under Statute Law (Bolar Provision) in the United States

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In the pharmaceutical/biotechnological fields, various acts of experiment and research are generally conducted for many years until a single product (drug) is successfully developed. Also, the academia, such as universities, makes significant contributions in these fields. Indeed, it has become common for universities to conduct research jointly with companies or research commissioned by companies in recent years. Therefore, it is important particularly for a foreign owner of a U.S. patent to sufficiently identify and understand the differences between the U.S. practice and the practice in his/her own country in determining whether an unauthorized person's act of using his/her patented invention within the United States for purposes of experiment or research corresponds to patent infringement.

Thus, the paper firstly analyzes recent U.S. court decisions related to common law exception and the points of contention. Then, it studies the development of court decisions related to application of the Bolar Provision, including decisions by lower courts. The paper then compares the identified/analyzed court decisions with the theories/court decisions in Japan and major European countries that are recognized to allow application of experimental use exception to a far broader scope of acts than the United States. Lastly, the paper attempts to examine the problems in the case of legislating experimental use exception provisions that could cover a broader scope of acts in the United States, and the relation with fair use of copyright.

I Common Law Exception

In the United States, the question of whether or not the effects of a patent right extend to "working of a patented invention for purposes of experiment or research" has been solely left to common law, tracing its origins to an opinion by Justice Story. This section introduces the recent U.S. court decisions related to common law exception and the points of contention.

[Recent court decisions]

1 Embrex, Inc. v. Service Engineering Corp. (2000)

In this case, the Court of Appeals for the Federal Circuit (CAFC) did not allow the common law exception for an act of experiment conducted for designing around a process invention. The case clarified anew that experimental use exception is only applied to extremely limited acts in the United States.

2 Madey v. Duke University (2002)

This case has clarified anew that common law exception is only applied in extremely limited cases.

[Points of Contention Related to Common Law Exception]

1 The de minimis exception

The de minimis exception is applied very narrowly, similar to the common law exception.

2 Legitimate business

In addition to the "use for profit" standard that had already been known, *Madey v. Duke University* clarified that even acts of nonprofit universities could constitute patent infringement, similar to research activities of ordinary companies, if the universities are engaged in legitimate business.

3 Philosophical inquiry

Since it was about 200 year ago that philosophical inquiry was indicated as one type of act subject to experimental use exception, the type of acts that people of those times could recognize from the language "philosophical inquiry" may not necessarily coincide with the type of acts that people nowadays can recognize.

II Statutory Exception: The Bolar Provision

This section firstly introduces the cases that

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have lead to the establishment of the Bolar Provision and the background of those cases, and summarizes the judicial precedents relating to application of the Bolar Provision, then attempts to analyze the modes of acts that are exempted from patent infringement based on the Bolar Provision.

1 Roche v. Bolar, the Drug Price Competition and Patent Term Restoration Act, and the Bolar Provision

[Court decisions]

Roche Products, Inc. v. Bolar Pharmaceuticals Co., Ltd. (1983, District Court)

Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc. (1984, CAFC)

[The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act)]

The Hatch-Waxman Act introduced a patent term extension system to allow R&D companies to restore a certain period of the patent term that has practically been consumed for obtaining approval of the approving authority. At the same time, it enabled use of the abbreviated new drug application (ANDA) system by generic drug manufacturers. With these two measure, the act aims to simplify the application for the pre-market approval for generic drugs and to promote entry of generic drugs into the market.

With the enactment of the Hatch-Waxman Act, the ANDA system was legislated, and provisions to allow patent term restoration under certain conditions and provisions to exclude acts of using patent inventions for collecting necessary information for obtaining FDA approval from patent infringement (35 U.S.C. §271(e)(1): the Bolar Provision) were added to the Patent Act.

The judicial decision in *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.* was reversed by legislation with the enactment of the Hatch-Waxman Act and introduction of the Bolar Provision.

2 Trend of court decisions over interpretation of the Bolar Provision

(1) Interpretation of "solely for uses reasonably related to"

This section analyses the following court decisions.

(i) *Scripps Clinic & Research Foundation v. Genentech, Inc.* (1986, District Court)

(ii) *Scripps Clinic & Res. Found. v. Baxter Travenol Labs., Inc.* (1988, District Court)

(iii) *American Standard, Inc. v. Pfizer Inc.* (1989, District Court)

(iv) *Telectronics Pacing Systems, Inc. v. Ventritex,*

Inc. (1992, CAFC)

(v) *Intermedics, Inc. v. Ventritex, Co.* (1993, CAFC)

(vi) *Chartex International PLC v. M.D. Personal Products* (1993, CAFC)

(vii) *Abtox, Inc. v. Exitron Corporation* (1997, CAFC)

(viii) *NeoRx Corp. v. Immunomedics, Inc.* (1994, District Court)

(ix) *Amgen Inc. v. Hoechst Marion Roussel, Inc.* (1998, District Court)

(x) *Biogen, Inc. v. Shering AG* (1996, District Court)

(xi) *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer* (2001, District Court)

(xii) *Integra Lifesciences I, Ltd. v. Merck KgaA* (2003, CAFC)

(2) Disputes over Interpretation of the Patented Inventions Covered by the Bolar Provision

(i) *Eli Lilly and Company v. Medtronic, Inc.* (1990, Supreme Court)

(ii) *Chartex International 1 PLC v. M.D. Personal Prods* (1993, CAFC)

(iii) *Abtox, Inc. v. Exitron Corporation* (1997, CAFC)

(iv) *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer* (2001, District Court)

[Summary of the trend of interpretation of the Bolar Provision]

The general application standards for the Bolar Provision, which have been indicated or confirmed in the above cases, can be summarized as below.

The first standard is the following: "we should ask: would it have been reasonable, objectively, for a party in the defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of the kind of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product?"

The second standard is that the Bolar Provision only indicates its application to acts solely for uses related to FDA approval, etc. and the underlying intent (such as an intent of commercialization) or alternative uses (such as tests related to patent licensing) are irrelevant to the application of the Bolar Provision.

The third standard is that the Bolar Provision covers acts conducted before the lapse of the patent that are "reasonably related to" obtainment of FDA approval for an already marketed drug.

The fourth standard is that the Bolar Provision also applies to matters other than those subject to patent term extension (drug products [including animal drugs], medical devices, food additives, and color additives).

III Comparison with the Experimental Use Exception Provisions in Japan and Europe

1 Comparison with the experimental use exception provisions in Japan

The report examines how the types of acts that are subject to experimental use exception under prevalent Japanese theories are treated in the United States.

(1) Patentability research/function research

In light of the application standard for U.S. common law exception, which is "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," the experimental use exception is unlikely to be applied when patentability research or function research has been conducted as part of the research activities of a company or a university. In addition, even if the patented invention was a drug invention, such research is unlikely to "contribute (relatively directly) to the generation of the kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product," which is an application standard for the Bolar Provision. On the other hand, the court has held that a use for confirming the effects disclosed in the patent specification was not patent infringement in *Whittemore v. Cutter*, so there could also be a view that either experimental use exception or the de minimis exception is applicable.

In any case, these acts may formally constitute patent infringement in the United States, but considering the extent of damage that could be inflicted on the patentee, it would be very unlikely for a patentee to file a patent infringement suit solely based on these acts.

(2) Experiments for the purposes of improvement/development

There are theories supporting exemption of experiments for the purposes of improvement/development from patent infringement also in the United States. A similar opinion is also stated in the amicus brief submitted by the Association of American Medical Colleges and others to request the Supreme Court to review the *Madey v. Duke University* decision.

However, the U.S. common law exception is only applied to an extremely narrow scope of acts, which are acts "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," and the exception is not applied if there is even "the slightest commercial implication." In addition, the experimental use is not applied even to acts for a non-commercial purpose, if the uses are "in keeping with the legitimate business." In this way, the United States does not possess the ideology of

making experiments for the purposes of improvement/development exempt from patent infringement.

Therefore, at present, in United States, there are limits in making all experiments for the purposes of improvement/development subject to experimental use exception even with the current interpretation of the common law exception and interpretation of the Bolar Provision. In order to make such acts subject to experimental use exception, a legislative resolution would be necessary, as mentioned in the statement submitted by the Solicitor General to the Supreme Court.

2 Comparison with the experimental use exception provisions in Europe

Major European countries also have experimental use exception provisions like Japan. However, unlike § 69(1) of the Japanese Patent Law, the provisions clearly state that the experiments must relate to the subject matter of the invention. In *Clinical Trials II* in Germany, the Supreme Court followed the indication in *Clinical Trials I*, and affirmed application of the experimental use exception to the defendant's acts as well as clearly indicated the following three important determination standards for application of experimental use exception.

(i) The sole requirement for application of the experimental use exception is that the evaluation or analysis derives findings [including usage] related to the subject matter of the invention, and those findings are directed to eliminating present uncertainties.

(ii) Existence of a research purpose beyond the present experimental purpose or an intention to use the experiment results for other purposes, such as for commercial profits, are irrelevant to determination of experimental use exception.

(iii) The following research is not subject to the exception: (a) research totally irrelevant to the patented invention; (b) research of a scale unjustifiable for an experimental purpose; (c) research conducted for the purpose of impeding or blocking the inventor's sales expansion of the patented product.

This section examines what the outcome would be if the above-mentioned U.S. cases were disputed in Germany, and categorizes the cases as follows.

Exception is likely to be applied both in the United States and Germany
<i>NeoRx Corp. v. Immunomedics, Inc.</i>
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i>
<i>Biogen, Inc. v. Shering AG</i>
<i>Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer</i>
Exception is likely to be applied in Germany, though not in the United States
<i>Embrex, Inc. v. Service Engineering Corp.</i>
<i>Scripps Clinic & Research Foundation v. Genentech, Inc.</i>
<i>Scripps Clinic & Res. Found. v. Baxter Travenol Labs., Inc.</i>
Exception is not likely to be applied either in the United States or Germany
<i>Madey v. Duke University</i>
<i>Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc.</i>
Exception may be applied in Germany depending on how the invention is perceived, though not in the United States
<i>Integra Lifesciences I, Ltd. v. Merck KGaA</i>

IV Study of Future Desirable Experimental Use Exception Provisions in the United States

This section attempts to examine the problems in the case of legislating experimental use exception provisions that could cover a broader scope of acts in the United States, and the relation to fair use of copyright.

1 Legislating experimental use exception provisions

As far as the U.S. court decisions are concerned, the modes of acts to which the experimental use exception is applied are extremely limited. Application of common law exception is not applied as long as there is a commercial purpose, and application of the Bolar Provision is likely to be operated strictly after *Integra Lifescience I, Ltd. v. Merck KGaA* in light of the purpose of legislation, as mentioned above.

On the other hand, theories supporting broad application of the experimental use exception had existed from the past. In order to achieve broad application of the experimental use exception as indicated by the theories, interpretation of the common law exception and statute law exception would not be sufficient, but a legislative solution would be the most realistic.

In fact, bills attempting to legislate experimental use exception provisions have actually been submitted to U.S. Congress in the past. There was an attempt to legislate the experimental use exception for uses of transgenic animals for experiment/research in 1988, but the

bill was not enacted.

Furthermore, in 1990, a bill attempting to introduce broad experimental use exception provisions similar to those in Japan and major European countries was submitted to Congress, and although it passed the House, it was not enacted.

Recently, a bill was submitted by Representative Rivers (Rivers Bill) in 2002. The bill was aimed at eliminating the adverse effects of genetic patents by providing limited restrictions to the effects of genetic patents. However, the bill was repealed without even passing the House.

These bills were submitted before the decisions of *Madey v. Duke University* and *Integra Lifescience I, Ltd. v. Merck KGaA*. Thus, considering that these two decisions have indicated an extremely narrow interpretation of application of the experimental use exception, it is highly probable that movements toward enacting a bill similar to the Rivers Bill will become more active in the future.

Also, it should be pointed out that, even if the experimental use exception were legislated in the United States in the future, compliance with the TRIPS Agreement must also be taken into consideration.

When a bill, which resembles the bill submitted in 1998 to exempt experimental uses of transgenic animal-related inventions or the bill submitted in 2002 to provide limited restrictions to the effects of genetic patents, is to be submitted in the future, it is necessary to sufficiently consider that the bill will not create "discrimination as to the field of technology" as set forth in Art. 27.1 of the TRIPS Agreement and it ensures the "legitimate

interests of the patent owner" as set forth in Art. 30 of the TRIPS Agreement.

2 Fair use under copyright law

Four determination standards for fair use are prescribed in § 107 of the U.S. Copyright Law: (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.

Comparing these with the determination standards for the common law exception, it is obvious that the fair use doctrine under copyright law leaves room for flexible application to various specific cases.

In order to apply the experimental use exception to such types of acts, it would be important to flexibly apply the exception according to the specific cases similar to the fair use doctrine under copyright law.



