

20 Trends in the U.S. Pro-Patent Policy in the Pharmaceutical and Biotechnology Fields —Focusing on the Hatch-Waxman Act—

Short-term Overseas Research Fellow: Toshihiko Asano^(*)

The United States is said to have achieved significant economic development, particularly in the information technology and biotechnology fields, through promotion of a “pro-patent” policy twenty years ahead of Japan. However, there is a concern that in the pharmaceutical and biotechnology fields, a pro-patent policy might have raised problems in relation to research tool patents and genetic patents. This report analyzes the current situation and trends in the United States from this viewpoint. The first part of this report gives an overview of what pro-patent policy was implemented in the United States, focusing on court decision and policy separately. The second part features the enactment of the Hatch-Waxman Act in 1984, which had a significant impact on the pharmaceutical and biotechnology fields. This Act can be regarded as legislation that typically realizes US balance-oriented policy. The second part reviews the background and legislative process of the Act, and studies future trends by examining the outcomes of various cases involving patent term extension, abbreviated new drug application (ANDA), and the Section 271(e)(1) exemption.

I Introduction

Three years have passed in Japan’s implementation of its intellectual property policy, and the country is also seeing signs of business pickup after a long-term recession. The U.S. pro-patent policy is thought to have begun in the time of recession in the 1980s, and after going through that time, the United States achieved significant economic development in the information technology and biotechnology fields. The first part of this report gives an overview of what pro-patent policy was implemented in the United States about twenty years ago, focusing on *court decision* and *policy* separately. The second part features the Hatch-Waxman Act, a patent policy measure that had a significant impact on the pharmaceutical and biotechnology fields, reviews its background and legislation process, and studies future trends by examining the outcomes of various cases involving patent term extension, abbreviated new drug application (ANDA), and the Section 271(e)(1) exemption.

The Hatch-Waxman Act can be regarded as a representative of legislation that realizes balance-oriented policy. When pro-patent policy has generated strains, this overall balancing mechanism that also covers case law appears to have played a coordinating role. There is a concern that in the pharmaceutical and biotechnology fields, a pro-patent policy might have raised problems in relation to research tool patents and genetic

patents. Analyzing the current situation and trends in the United States will be a great help for Japan.

II History of U.S. Pro-Patent Policy

The term “pro-patent” refers to patent-focused policies and judgments emphasizing protection of a patentee’s rights, but it is not so frequently used in the United States. There is less point in categorization by *pro-patent* and *anti-patent*. Rather, it is more important to maintain a balance between “protection policy under the patent system” and “competition policy under the antitrust system,” thereby keeping the overall economy in the best condition for development.

The U.S. Constitution promulgated in 1788 after the independence guarantees citizens the right to register patents for promoting the advance of science and technology. The period from the foundation as a nation until around the First World War, centering on the time of President Lincoln in the second half of the 19th century, can be regarded as the first pro-patent era of the United States. In the anti-patent era from the Great Depression (1929) through to the 1970s, an antitrust policy was thoroughly pursued. Having gone through the stalemate of the Vietnam War and the two oil crises and experienced the weakening of its international competitiveness and the economic threat of Japanese industry, the United States saw a trade

(*) Currently Intellectual Property Department, Administration Division, Astellas Pharma Inc.

deficit in 1979 for the first time in its history. In the same year, the President's Address on Industrial Innovation Initiatives (Carter's Address) was presented, advocating many measures under a pro-patent policy (e.g. the establishment of the Court of Appeals for the Federal Circuit (CAFC) and the enactment of the Bayh-Dole Act). These measures have been put into practice from the 1980s until today, and this period forms the second pro-patent era.

Meanwhile, in Japan, intellectual property started to gain more attention in the second half of the 1990s when Japan's conventional method of technology development became no longer applicable and the recession triggered by the collapse of the bubble economy lingered. Following Prime Minister Koizumi's policy speech in February 2002, the Japanese government presented its basic scheme for making Japan an intellectual property-based nation in the *Intellectual Property Policy Outline*. Furthermore, using the U.S. Bayh-Dole Act (1980) as a model, the government promoted industry-academia collaboration and commercialization of patented inventions by applying Article 30 of the Law on Special Measures for Industrial Revitalization, which is called the Japanese Bayh-Dole system. In line with the establishment of the CAFC in the United States (1982), Japan also established the Intellectual Property High Court (2005). Thus, although behind the United States by about twenty years, Japan's pro-patent policy has already begun to bring about results.

III Changes in the Pro-Patent Trends Seen in Court Decisions

Determining court decisions as being in the pro-patent trends or anti-patent trends

Representative court decisions are analyzed in chronological order from the following four perspectives:

- (1) Should patentability be found in such types of subject matter that have never been deemed to be patentable before? (expansion of the scope of patentable subject matter)
- (2) How should utility and non-obviousness be determined?
- (3) To what extent should the scope of patent be expanded through claim interpretation? (criteria for applying the doctrine of equivalents)
- (4) What is the basis for defining the extent of exception to patent infringement?

In *Brenner v Manson* in the anti-patent era (1966), the Supreme Court determined utility, a

requirement under Section 101 of the U.S. Patent Act, pointing out that it was not sufficient in proving the compound's utility to argue that it was the "subject of serious scientific investigation"; patentability would not be found unless the compound had practical utility. In *Benson* (1972), the Supreme Court addressed the issue of patentable subject matter also provided Section 101, and denied the patentability of a mathematical formula or a conversion algorithm itself.

In *Chakrabarty* in the pro-patent era (1980), the Supreme Court determined that genetically-engineered micro organisms should be deemed to be included in the scope of patentable subject matter provided under Section 101, holding that there was nothing in the language of the Patent Act to exclude living things from the scope of patentable subject matter. In *Diehr* (1981), the Supreme Court determined that the process that used a mathematical formula and digital computer was eligible for patentable protection under Section 101 of the Patent Act. In *Warner-Jenkinson* (1997), the Supreme Court upheld the common law doctrine of equivalents that had been established by the CAFC, pointing out that "the Court adheres to the doctrine of equivalents; the determination of equivalence should be applied as an objective inquiry on an element-by-element basis." However, in *Madey v. Duke University* (2002), it was clearly declared that even experimental use at university does not qualify for the experimental use defense, if the act is in furtherance of the alleged infringer's legitimate business and is "not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." This suggests that the protection-oriented tendency along with the pro-patent trends is likely to have an influence on freedom of study or research.

Some court decisions recently made show obvious changes in trends from the pro-patent era so far. In *Festo*, the en banc court of the CAFC ruled in 2000 that estoppel arises from any amendment that narrows a claim to comply with the Patent Act, and when estoppel applies, it bars any claim of equivalence for the element that was amended (strict approach; complete bar). This ruling unilaterally overturned the precedents on the doctrine of equivalents, and shocked companies all around the world including U.S. companies. In 2002, the Supreme Court rejected the CAFC's complete bar and adopted a flexible bar for applying prosecution history estoppel, ruling that prosecution history estoppel was applicable not only to amendments intended to

narrow the patented invention's subject matter but also to any narrowing amendment, including an amendment to correct defects in description. In *Housey* (2004), Housey, the holder of U.S. patents for an assay research tool using animal cells based on ambiguous and too broad claims, coercively offered to license the patented method to pharmaceutical companies across the world, and sued them if they did not accept the offer. The patent application filed in Japan in respect of this invention was rejected as lacking novelty or inventive step, and the CAFC determined that the patents should be invalid. In *Fisher* (2005), following the Supreme Court decision on *Brenner v. Manson* in 1966, the CAFC pointed out that Fisher's specification failed to provide specific gene expression data of the claimed ESTs but only disclosed general uses of ESTs (molecular marker, micro-array technology, primers), and an application must contain the disclosure to establish a "specific and substantial utility" for the claimed invention. Consequently, the court supported the decision by the Board of Appeals to reject the patent application.

IV Hatch-Waxman Act

1 Legislative History of the Hatch-Waxman Act

Background of the enactment of the Hatch-Waxman Act

In 1938, the Federal Food, Drug, and Cosmetic Act (FDCA) was established for the purpose of ensuring safety of drug products before placed in the market. Triggered by the thalidomide scandal, the Kefauver-Harris Amendment was established in 1962, requiring more data to be submitted in the process of obtaining approval of new drugs at the Food and Drug Administration (FDA) and also requiring notification to be given of investigational new drugs (IND) to the FDA prior to conducting clinical tests. As a result, the period from filing a new drug application (NDA) until obtaining approval was prolonged; it took more than ten years to complete R&D, from conducting pre-clinical tests and clinical tests until filing an NDA, and then following the new drug approval procedure before the FDA, which would eat up most of the term of a patent provided under the U.S. Patent Act of that time, 17 years. There were strong calls for legislation to restore the term of patent after approval to make up for the time consumed for examination proceedings at the

FDA. In 1980, legislation for patent term restoration was brought to deliberation for the first time at the 96th Congress. At the 97th Congress from 1981, Senator Charles McCurdy Jr. Mathias submitted a bill for patent term restoration, which was finally rejected by the House of Representatives due to vigorous protest lobbies by generic drug manufacturers and also by consumer groups opposing the bill.

On the other hand, the enormous wall that confronted generic drug manufacturers at that time was the tightened examination procedures for FDA approval. After the amendment, NDA was also required for approval of generic drugs that arose from original drugs approved in 1962 and thereafter, and approval was not granted unless clinical tests that had already been conducted by the original drug manufacturer were conducted anew. Generic drug manufacturers faced difficulties filing NDAs, which would eliminate market mechanism principles. Therefore, it was necessary to make the abbreviated new drug application system (ANDAs: only required materials relating to bioavailability and bioequivalence and allowed omission of pre-clinical and clinical reports) also applicable to generic drugs arising from new drugs approved since 1962.

98th Congress and *Roche v. Bolar*

At the 98th Congress, Senator Mathias and Representative Mike Synar submitted bills for patent term restoration in June 1983. Meanwhile, in July 1983, Representative Henry A. Waxman, supporting generic drug manufacturers and aiming to promote the sale of generic drugs, submitted a bill for drug price competition.

The CAFC decision on *Roche v. Bolar* was rendered in April 1984 under such circumstances. The defendant Bolar, during the term of the patent for the sleeping pill marketed by Roche, attempted to begin necessary testing for filing an NDA (it would take about two years to collect the necessary data for FDA approval). Roche charged Bolar with patent infringement. The district court denied infringement, holding that Roche did not suffer any substantial loss from Bolar's filing of an NDA, and therefore Bolar's act was *de minimis*. Against this decision, the CAFC determined the use of the patented invention in the testing for FDA approval of a generic drug as patent infringement, stating that the experimental use rule cannot be construed so broadly when that inquiry has definite, cognizable, and not insubstantial commercial purposes. In response to Bolar's argument that "if testing prior to the

expiration of the patent term were prohibited, it would in effect extend the term of Roche's patent for two years," the CAFC concluded that the patentee's interests and the generic drug manufacturer's interests should be adjusted through legislation, not through experimental use exception.

Driven by the *Roche v. Bolar* decision, rapid progress was made toward the enactment of the Hatch-Waxman Act at the 98th Congress. Representative Waxman worked hard for a big negotiation between the most important organizations concerned, the Pharmaceutical Manufacturers Association (PMA), the party that wished for the introduction of the patent term restoration system, and the Generic Pharmaceutical Industry Association (GPIA), the other party that wished for the introduction of the ANDA system. Under the initiative of Representative Waxman (Democrat) and Senator Orrin G. Hatch (Republican), a compromise bill was born as a package bill that integrated the bill for patent term restoration and the bill for drug price competition. This package bill was finally integrated into the bill to amend the patent laws of the United States submitted by Senator Mathias. On September 24, the Drug Price Competition and Patent Term Restoration Act of 1984, which is generally called the Hatch-Waxman Act, was enacted.

2 Patent term extension and ANDA

Patent term extension is provided in Section 156 of the Patent Act. The term for a patent for a human drug product shall be extended by the time consisting of half of the period from the date of notification of IND until the date of filing of NDA, plus the period from the date of NDA until the date of approval, not exceeding five years. The ANDA system is provided in Section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C.A. §355) (j). Under this system, original drug manufacturers are required to disclose information on patents and data exclusivity in the Orange Book, whereas generic drug manufacturers are required, upon filing an ANDA, to attach a patent certification to the application form so as to make a statement on the relevant patent owned by the original drug manufacturer and listed in the Orange Book. There are four types of patent certification as follows:

Paragraph I: The patent information has not been filed.

Paragraph II: The patent has expired.

Paragraph III: Indicate the date of expiration for the patent currently in force, and declare that the generic drug will be released after the expiration of the patent.

Paragraph IV: Indicate that the patent currently in force is invalid or will not be infringed by the new drug subject to the ANDA.

Section 505(j) of the FDCA also includes the following provisions on ANDA.

- The FDA grants 180-day exclusivity period to the first generic drug manufacturer that has filed a Paragraph IV ANDA for a particular drug.
- Generic drug manufacturers are also required to notify the original drug manufacturer that owns the patent for the original drug of the filing of an ANDA during the life of the patent. If the original drug manufacturer brings an action for infringement against the ANDA applicant within 45 days from the date of notification, approval may be stayed for 30 months from the date of notification. Approval shall be granted immediately if the applicant wins the case.
- Generic products shall be excluded from the market for a fixed period from the date of approval, i.e. five years if the new drug contains a new compound or three years if the new drug relates to a new use.
- An ANDA may be accepted after the expiration of four years even within the five-year protection period if the applicant proves that the patent for the original drug is not infringed.

The provision on ANDA can also be found in Section 271(e)(2) of the Patent Act. According to this provision, it shall be deemed to be an act of infringement to submit, during the life of the patent, an ANDA or NDA with a Paragraph IV Certification for a generic drug.

3 Cases arising from patent term extension and ANDA

Cases over patent term extension

Both in *Merck v. Tava* (2003) and *Pfizer v. Dr. Reddy's* (2004), the point of issue was how to treat "salt as an active ingredient," but they are different from each other in that the former focused on the construction of the claims whereas the latter focused on the construction of the product subject to term extension. In *Merck v. Teva*, Merck omitted inclusion of the salt in the

process claims for a use invention. Teva filed an ANDA for the same salt as Merck's patented product and argued that Merck's patent was invalid or not infringed. On the other hand, in *Pfizer v. Dr. Reddy's*, Dr. Reddy's filed a paper NDA for the salt in a different form from that of Pfizer's product, based on the clinical data that Pfizer had provided to the FDA. In both cases, the generic drug manufacturers' filing of applications for FDA approval was determined as patent infringement. In light of the legislative purpose of the Hatch-Waxman Act, the decisions in these cases can be deemed to be appropriate, because the patent term extension system would have become meaningless if during the period of a restoration extension, approval had been obtainable for generic drugs that consisted of the same active ingredient as the patented product, with the only difference being the salt.

Cases over ANDA

In 2003, two noteworthy decisions were rendered by the CAFC on how to deal with a use patent in the following hypothetical case: a new drug manufacturer, in the process of filing an NDA for a drug to treat a disease X, has obtained FDA approval by listing a substance patent and a use patent regarding the treatment of Disease X in the Orange Book and sold the drug, and then discovered that the drug is also effective in treating another disease Y, and obtained the second use patent regarding the treatment of Disease Y. According to the conclusion drawn from the CAFC decisions, if a generic drug manufacturer files an ANDA for a drug to treat Disease X upon the expiration of the substance patent and the first use patent, the new drug manufacturer shall not be required to list the second patent in the Orange Book, and the manufacture and sale of the drug by the generic drug manufacturer shall not be regarded as infringement unless the generic drug manufacturer recommended the use of the generic drug for the purpose of treating Disease Y, which would constitute an act of inducing infringement.

In *Mylan Pharmaceuticals, Inc. v. Thompson* (2001), in which the listing of false information in the Orange Book was disputed, Bristol-Myers Squibb (BMS) listed its patent in the Orange Book as a use patent for the major component, despite the fact that the patent related to a metabolic product that should not have been listed in the book. BMS charged Mylan with infringement for having filed an ANDA, and was

granted a 30-month stay of approval. Mylan filed a counterclaim against the FDA and BMS for violation of the Antitrust Act. The district court upheld Mylan's claim and ordered the FDA to delete the patent from the Orange Book and approve the ANDA immediately.

Acts charged by the FTC

Before the revision of the ANDA system in 2003, the FTC charged brand-name drug manufacturers for concluding a settlement agreement with generic drug manufacturers that had filed the first Paragraph IV ANDA, thereby preventing other generic drugs from entering the market.

Amendment of the FDA regulations on ANDA and the Hatch-Waxman Act in 2003

From the perspective of protecting generic drug manufacturers against unjustifiable interference, the FTC developed a recommendation report in July 2002. In light of the FTC report, on October 21, 2002, President Bush proposed a bill to amend the FDA regulations with the aim of permitting only one 30-month stay of approval per drug product and ensuring appropriate listing of patents in the Orange Book. The amended regulations were put into force on August 18, 2003.

Furthermore, the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" was enacted on December 8, 2003, resulting in amending some provisions in relation to the Hatch-Waxman Act.

- The first ANDA applicant shall be required to forfeit the 180-day exclusivity period under circumstances including the failure to market within a specified time frame.
- Any agreements made between new drug manufacturers and generic drug manufacturers regarding the manufacture or sale of a generic drug must be filed with the Assistant Attorney General and the FTC for review within 10 days after the agreements are executed.

4 Section 271(e)(1) of the Patent Act and Merck v. Integra

Section 271(e)(1) exemption (generally called Bolar exemption or safe harbor exemption)

In light of its legislative purpose—to reverse the *Roche v. Bolar* decision that had determined that testing for FDA approval during the life of a patent should constitute patent infringement, it

may be reasonable to construe this provision to be only applicable to ANDAs for generic drugs, but such limitation cannot be found in the text. The text of this provision merely stipulates that the patent shall not be infringed by the exploitation of the patented invention “solely for uses reasonably related to the development and submission of information under a Federal law.” The interpretation of this part has caused many lawsuits.

***Eli Lilly and Co. v. Medtronic, Inc.* (1990; Supreme Court)**

The point at issue in this case was how to define the scope of patented inventions to which the Section 271(e)(1) exemption was applicable. Eli Lilly argued that the exemption was applicable only to drugs and not applicable to medical devices. The Supreme Court, in light of the legislative purport of the Hatch-Waxman Act, recognized the applicability of the Section 271(e)(1) exemption to any products for which patent term restoration may be sought under the Act. Consequently, it was clearly established that the Section 271(e)(1) exemption was applicable to patented inventions relating to drug products (for humans or animals), medical devices, or food additives or color additives.

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

In this case, the district court presented a standard for applying the Section 271(e)(1) exemption shown below.

Whether or not it would 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 kinds of information that were likely to be relevant in the processes by which the FDA would decide whether to approve the product.

This standard was confirmed by the CAFC and has been adopted as the “Intermedics test” in later cases.

***AbTox, Inc. v. Exitron Corporation* (1997; CAFC)**

The CAFC stated that it must follow the Supreme Court's broader holding in *Eli Lilly v. Medtronic*, and applied Section 271(e)(1) to the use of the Class II device in the testing for FDA approval. Thus, the CAFC has determined that Section 271(e)(1) was also applicable to a subject that is not eligible for patent term extension (the

Class II device).

***Infigen, Inc. v. Advanced Cell Technology, Inc.* (1999; District Court)**

Advanced Cell Tech. was charged by Infigen with patent infringement for having launched the development of a transgenic cow that would produce milk containing recombinant human serum albumin by using Infigen's patent for the technology to produce recombinant human product from a transgenic cow. The defendant argued that its use of the patented products and method came within the Section 271(e)(1) exemption because it was working on the preliminary steps of a product from a transgenic cow that would need FDA approval. However, the district court denied the applicability of the exemption, holding that Section 271(e)(1) applied only to those patents covering products defined under Section 156(f), which were eligible for patent term extension, and the patent used by the defendant did not fall within the scope of drugs or medical devices specified under Section 156.

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

In the screening phase of the taxane R&D program, BMS developed a structure-activity relationship database using more than 1,000 taxane derivatives, including RPR's patented intermediates. BMS finally developed taxane analogs and obtained FDA approval for them. RPR argued that its intermediates should be excluded from the scope of Section 271(e)(1) because they were not end products eligible for patent term extension. The district court determined that patented inventions provided in Section 271(e)(1) were not limited to such products that were eligible for patent term extension.

RPR also claimed that BMS's use of the patented intermediates was not “solely for uses reasonably related to” the submission of information to the FDA. BMS argued that the data of the initial screening tests were included in the information to be submitted to the FDA with an IND application and NDA. The district court, by applying the Intermedics test, upheld BMS's argument.

As shown in the trends of the court decisions before *Merck v. Integra*, with the exception of the narrow holding in *Infigen v. Advanced Cell Tech.*, Section 271(e)(1) was determined to be applicable to a wider range of experiments and research activities for the development of new drugs.

Integra LifeSciences I, Ltd. v. Merck KGaA:
Outline of the case and district court decision

Integra owned patents for RGD peptide, which plays a critical role in creating new blood vessels (angiogenesis). Merck requested the Scripps Research Institute to specify compounds that could serve as angiogenesis inhibitors from among candidate compounds including Integra's patented compounds, and successfully discovered a cyclic peptide EMD121974. Having been aware of this, Integra charged Merck with patent infringement. The district court, denying the applicability of the Section 271(e)(1) exemption to Merck's experimental activities, found infringement of Integra's four patents, and upheld the claim for damages of 15 million dollars as a reasonable royalty.

CAFC decision (2003)

The CAFC held that the Scripps-Merck activities were not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds, and therefore Merck's activity was not "solely for uses reasonably related" to clinical testing for FDA. Consequently, denying a broad interpretation of Section 271(e)(1), the CAFC affirmed the district court decision, and remanded the case for further examination on the amount of damages. The main points of the CAFC's decision are as follows: "extending Section 271(e)(1) to embrace all aspects of new drug development activities would ignore its language and context with respect to the Hatch-Waxman Act"; "the FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval."

Dissenting opinion by Judge Newman

Judge Rader wrote the majority opinion on this case on behalf of the three-judge panel of the CAFC. Judge Newman dissented in part in a separate opinion.

- The subject matter of patents may be studied in order to understand it, or to improve upon it, or to find a new use for it, or to modify or "design around" it. Were such research subject to prohibition by the patentee the advancement of technology would stop, and therefore prohibition of research cannot be squared with the framework of the patent law.
- The common law exemption is not unlimited. Indeed, it is a narrow exemption, for it must preserve the patentee's incentive to innovate, an incentive secured only by the right to

exclude.

- Although the purport of Section 271(e)(1) originates in exempting experimental use for FDA approval of generic drugs from liability, the section should be interpreted more broadly, as determined by the Supreme Court in *Eli Lilly v. Medtronic*, to also apply to the IND application in question.
- The panel majority appears to view the Integra patents as for a "research tool." However, the RGD-containing peptides of the Integra patents are not a "tool" used in research, but simply new compositions having certain biological properties.

With respect to Judge Newman's dissenting opinion, Judge Rader made the following comment: "The common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the "FDA exemption," i.e. Section 271(e)(1)."

Merck KGaA v. Integra LifeSciences I, Ltd.
(2005; Supreme Court)

The Supreme Court, as of June 13, 2005, reversed the CAFC's majority opinion by a unanimous decision, recognizing the scope of the Section 271(e)(1) exemption more broadly to include the use of the patented compounds in preclinical research at least as long as there was a reasonable basis to believe that the experiments would produce the types of information relevant to an IND or NDA. The Supreme Court thus quashed the CAFC decision and remanded the case for further examination. The main points of the Supreme Court's holding can be summarized as follows.

- (i) Section 271(e)(1) exemption extends to preclinical tests.

The statutory text makes clear that Section 271(e)(1) provides a wide berth for any uses of patented inventions reasonably related to the development and submission of any information under the FDCA. This necessarily includes preclinical studies pertaining to the use of patented compounds that could be the subject of an FDA submission.

- (ii) Conformity with the FDA's regulations on good laboratory practices (GLP) is not necessarily required for preclinical tests.

- (iii) Section 271(e)(1) exemption is applicable even when the drugs or experimentation thereon are not ultimately submitted to the FDA.

The CAFC disregarded the reality that, even

at late stages in the development of a new drug, scientific testing was a process of trial and error, because there was no way of knowing whether an initially promising candidate would prove successful over a battery of experiments, and this was the reason to conduct the experiments.

The Supreme Court did not express a view about whether, or to what extent, Section 271(e)(1) exempted from infringement the use of research tool patents in the development of information for the regulatory process.

Consideration

In *Merck KGaA v. Integra LifeSciences I, Ltd.*, the Supreme Court turned down the CAFC's narrow interpretation of the scope of the Section 271(e)(1) exemption. The Supreme Court's determination seems to be in line with Judge Newman's dissenting opinion at the CAFC. In her dissenting opinion, Judge Newman also pointed out that Integra's peptide was not research tool.

In Japan, an activity to use a patented invention for the purpose of improving or circumventing it would be exempted from liability for infringement as "experimental or research exception" under Section 69(1) of the Japanese Patent Law. The scope of exemption under Section 69(1) of the Japanese Patent Law cannot be said to be broad at all, and Someno's theory is commonly accepted that the scope of exemption should be limited to such activities as aimed to achieve technological progress using patented inventions per se as research subjects, which corresponds to Judge Newman's view. If *Merck v. Integra* took place in Japan, Section 69(1) would be applied unless Integra's patent was regarded as a research tool. Judge Rader stressed protection for research tool patent holders. His dissenting opinion presented in the *Fisher* case in 2005 also gave consideration to research tool patents. The US Supreme Court refrained from determining whether or not the use of research tool patents was eligible for the Section 271(e)(1) exemption. This resulted in the possibility that the use of research tool patents in R&D of new drugs would be treated in different manners in the United States and Japan in terms of exemption from liability for infringement.

According to the language of Section 271(e)(1), "solely for uses reasonably related to the development and submission of information under a Federal law," the exception would be applicable only in cases where drug manufacturers, those manufacturing new drugs and generic drugs, file applications for FDA approval, and would not

extend to basic research at universities and research institutes. With respect to the use of research tool patents, which is obviously irrelevant to the filing for FDA approval, the Supreme Court decision has not made any change in the situation where the common law experimental use exemption can hardly be expected to be applied, as suggested by the CAFC decision in *Madey v. Duke University*.

Comparing the US Supreme Court decision in *Merck v. Integra* with the Japanese Supreme Court judgment in 1999 (1998 (Ju) No. 153), they have in common the broadly interpreted scope of exemption under the existing provisions, but differ from each other in the theoretical concepts supporting the interpretation. The Japanese Supreme Court denied infringement by applying Section 69(1) of the Japanese Patent Law to the clinical test conducted by the generic drug manufacturer, before the expiration of the patent held by the original drug manufacturer, to obtain manufacturing approval. The Supreme Court gave the following reason for the judgment: "if the test did not fall within the scope of 'experiment' provided in Section 69(1), it would bring about the same effect as the extension of the patent term and prevent third parties from freely exploiting the patented invention, which is contrary to the foundation of the patent system." This is exactly what the defendant argued in *Roche v. Bolar*, which was rejected by the CAFC as an "issue that should be solved through legislation" and subsequently reversed by the enactment of the Hatch-Waxman Act. In *Merck v. Integra*, the US Supreme Court determined the scope of Section 271(e)(1) by focusing on the interpretation of the phrase "solely for uses reasonably related to," while excluding from consideration the "balance with patent term extension."

V Conclusion: Trends in US Patent Policy

The Hatch-Waxman Act was enacted as an ideal balancing mechanism aimed at emphasizing patent protection and also promoting competition. However, around 2000, the Act came to be used for anticompetitive purposes against its legislative purport, revealing strains in the mechanism. In 2003, amendment was made to the Act immediately in order to seal up the loopholes that caused such abuse, and the strains have been removed quickly by administrative and legislative means. In October 2003, the Federal Trade

Commission (FTC) published a report entitled “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,” which discussed solutions that are expected to properly correct various anticompetitive problems that may arise from the pro-patent policy.

In 2004, the National Academies of Science (NAS), in its report in 2004 entitled *A Patent System for the 21st Century*, pointed out the occurrence of new strains on the patent system. Reform proposals presented in this report have been adopted for amendment bills and are expected to contribute to developing a new patent system free from strains in the near future. Compared with some CAFC decisions made in the 1990s that placed excessive emphasis on patentees’ rights, the Supreme Court decisions recently made (*Festo*, *Merck v. Integra*) show obvious changes in trends, as if attempting to remove the strains. However, since the Supreme Court refrained from making a determination on the issue of research tool patents in *Merck v. Integra*, the decision in *Madey v. Duke University*, a representative pro-patent decision, still serves as common law. Considering that this issue is also discussed at the NAS, we can expect that strains arising from pro-patent policy will be corrected and a balanced system will be developed in the near future.

