

Washington Journal of Law, Technology & Arts

Volume 7
Issue 4 *Chief Judge Rader's Contribution to
Intellectual Property Law and Practice*

Article 6

4-1-2012

Chief Judge Rader's Contribution to Comparative Patent Law

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Toshiko Takenaka, *Chief Judge Rader's Contribution to Comparative Patent Law*, 7 WASH. J. L. TECH. & ARTS 379 (2012).

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CHIEF JUDGE RADER'S CONTRIBUTION
TO COMPARATIVE PATENT LAW

Toshiko Takenaka *
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Cite as: 7 Wash. J.L. Tech. & Arts 379 (2012)
<http://digital.law.washington.edu/dspace-law/handle/1773.1/1127>

ABSTRACT

Chief Judge Rader influences patent jurisprudence in other nations through his interaction with judges and lawyers from these jurisdictions. He also uses the comparative method to gain insights from experiences in these jurisdictions to improve U.S. patent jurisprudence. This Article discusses opinions authored by Chief Judge Rader from the comparative law perspective. It discusses his influence on European and Japanese patent jurisprudence in the three areas: the (I) patent eligibility, (II) nonobviousness, and (III) enablement-written description requirements. Judge Rader likewise used his knowledge of foreign jurisprudence to interpret U.S. patent statutes and to develop doctrines in these areas.

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INTRODUCTION

This author met Chief Judge Randall Rader for the first time at the Association of American Law School (AALS) annual meeting in Washington, D.C. in 1997. Since then, the judge has been a great mentor and inspiration for academic research and writing. He invited me to spend time in his chambers and work with his fulltime law clerks on cases assigned to him. The experience working with him gave invaluable insights into reading opinions and analyzing U.S. case law. Judge Rader has given similar opportunities not only to U.S. law students, but also to European and Japanese lawyers who attended the LL.M. programs in which he teaches as an adjunct professor. He is a frequent speaker for patent-related seminars and conferences and engages in debates with European and Japanese judges on issues that parties present in patent infringement litigation filed in their courts. Just as he is one of the most influential persons in my academic career, he has made a substantial impact on the development of professional and academic careers for key people in the European and Japanese IP community.

Such influences appear in European and Japanese case law through opinions and briefs authored by judges and lawyers who are familiar with U.S. patent jurisprudence. Although courts in civil law countries, such as Japanese courts, do not have a tradition

of citing cases, particularly cases from foreign jurisdictions, European and Japanese judges are open to a well-reasoned argument regardless of the source. Judges who are exposed to U.S. ideas through work with Chief Judge Rader or his presentations may readily find merit in arguments in briefs prepared by U.S.-trained lawyers. Such an influence is confirmed by similarity in discussions and reasoning on important patentability and infringement issues between opinions authored by European and Japanese judges and by Chief Judge Rader.

Chief Judge Rader's knowledge on patent jurisprudence in foreign countries also brings great benefit to the U.S. patent community. He uses the comparative law method for analyzing issues presented to his courts and highlights various features of the U.S. patent system that contrast with foreign patent systems, helping U.S. legal professionals develop an in-depth understanding of patent policies underlying the parties' disputes from the global perspective. His openness to ideas from foreign countries and his effort to develop the best practices for enhancing patent policies naturally have brought some aspects of U.S. patent system more in line with the rest of the world.

This Article discusses opinions authored by Chief Judge Rader from the comparative law perspective. It compares his opinions with opinions authored by European and Japanese judges and discusses his influence in European and Japanese patent jurisprudence and vice versa. This Article focuses on three areas—the (I) patent eligibility, (II) nonobviousness, and (III) enablement/written description requirements—in which Judge Rader used his knowledge on foreign jurisprudence to interpret the U.S. patent statute and to develop doctrines. This Article also reviews opinions authored by European and Japanese judges with respect to Judge Rader's work in these three areas to discuss his contribution to comparative patent law.

I. PATENT ELIGIBILITY

A. *The United States*

An important issue in patent law is whether an invention fits within the subject matter that is eligible for a patent. The U.S.

patent system benefits from Chief Judge Rader's broad knowledge of foreign patent systems when it comes to assessing patent eligibility. It is very rare for U.S. courts, at least in patent cases, to take account of statutes and jurisprudence of foreign countries. Chief Judge Rader changed this tradition and used comparative law to support his views. In *In re Bilski*,¹ Chief Judge Rader emphasized the broad scope of patent eligible subject matter under the U.S. Patent Act in comparison to that of the European Patent Convention.

Unlike the laws of other nations that include broad exclusions to eligible subject matter, such as European restrictions on software and other method patents . . . and prohibitions against patents deemed contrary to the public morality . . . U.S. law and policy have embraced advances without regard to their subject matter.²

Chief Judge Rader believes that this broad patent eligibility gives the U.S. patent system enough flexibility to embrace unknown fields of inventions and to guarantee incentives for new innovations, which leads the U.S. to be a top innovation-driven country in global competition. To maintain this broad eligibility, he urges limiting exclusions from patent eligibility to three items expressly endorsed by the Supreme Court: (1) laws of nature; (2) natural phenomena; and (3) abstract ideas.³ Nevertheless, he concluded that the claims at issue in *Bilski* should be rejected for lack of eligibility simply because they were directed to an abstract idea.⁴ He explained that the reason why an abstract idea is excluded from patent eligibility is to adhere to the constitutional goal of the patent system: “[T]he [Patent] Act intends, as section 101 explains, to provide ‘useful’ technology”; thus, “[a]n abstract idea must be applied to (transformed into) a practical use before it qualifies for protection.”⁵

¹ 545 F.3d 943 (Fed. Cir. 2008).

² *Id.* at 1012 (Rader, J., dissenting) (citations omitted).

³ *Id.*

⁴ *Id.* at 1011

⁵ *Id.* at 1013.

Inspired by Judge Rader, Judge Haldane Robert Mayer also used comparative law to support his view by citing the definition of statutory invention under the Japanese Patent Act (JPA) and the Patent Act of the Republic of Korea in his dissenting opinion.⁶ Relying on the U.S. Supreme Court's definition of eligibility, "the application of the law of nature to a new and useful end,"⁷ he argued that the scope of patent eligibility should include only technological subject matter because "applying laws of nature to new and useful ends is nothing other than 'technology'" as these foreign patent acts define patent eligible inventions. As a result, he concluded that business methods should be excluded from patent eligibility.

B. Japan

Contrary to Judge Mayer's restrictive interpretation of patent eligibility, the definition of invention under the JPA does not categorically exclude business methods. The JPA defines a statutory invention as the highly advanced creation of technical ideas that utilize a law of nature.⁸ The statute requires a highly advanced level of creation because of the need to distinguish the subject matter of the patent from that of the utility model, which is a type of *petite* patent that requires only a low level of nonobviousness or inventive step.⁹

The key to distinguishing patent-eligible subject matter from ineligible subject matter under JPA is the utilization or application of a law of nature. Some Japanese judges interpret "laws of nature" broadly in the same manner as Chief Judge Rader interprets "an abstract idea" to include any law or principle that can be applied to a practical use. They may find a statutory invention with respect to a business method as long as the method provides a concrete and useful result regardless of the nature of the practical use.

Such a broad interpretation is highlighted in the phoneme index

⁶ *Id.* at 1003.

⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

⁸ Japanese Patent Act (JPA), art. 2, para 1.

⁹ Compare JPA art. 29, para. 2 with Japanese Utility model Act, art. 3, para. 2.

dictionary case.¹⁰ Reviewing an appeal from the Japan Patent Office (JPO), Japan's IP High Court found statutory invention with respect to a claim for a method of finding words in a bilingual dictionary. In this case, the court held that the method relied on a law of nature based on a theory that Japanese-speaking people generally recognize consonants in English words more easily than vowels. The claimed method uses this law of nature to help a non-English speaker, such as a native Japanese speaker, to find an English word in the dictionary by utilizing a unique phoneme index multi-element matrix. The matrix includes rows consisting of four elements of a particular English word: (1) a consonant in the word; (2) the vocal accent and consonants (phonetic symbols); (3) spelling; and (4) translation. Columns consist of English words in alphabetical order. Because Japanese people generally recognize consonants in English words more easily than vowels, they can find the same combination of consonants in the matrix and look up the word they are looking for in the dictionary.

The broadest claim does not require a computer or machine, and thus the method can be implemented manually. The JPO rejected the claim for lack of statutory invention because it found that the claim is directed to a mental process or a scheme arbitrary to the party who set out the scheme. The IP High Court reversed the JPO's rejection because it found that the method utilizes a law of nature to solve a problem. In defining the claimed invention, the court held that the method solves a problem (i.e. finding an English word without knowing the spelling of the word) by utilizing the ability to recognize consonants in English words more easily than vowels. It found that this ability is a law of nature because the useful result, finding an English word, is not unique to a particular individual, but is available to all Japanese users. In other words, a method that utilizes a law of nature constitutes a statutory invention if it provides a useful and concrete result. Accordingly, the interpretation of a law of nature under the JPA adopted by the phoneme index case is much broader than a narrow definition that includes only a principle or idea deriving from a scientific theory.

¹⁰ Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High C.] Aug. 26, 2008, Hei 20 (gyō-ke) 10001, Saikō Saibansho Saibanrei Jōhō [Saibanrei Jōhō], <http://www.courts.go.jp>. Please note that the party of this case is not disclosed.

It is likely that the interpretation includes a principle deriving from purely empirical or non-theoretical ideas.

Just as Chief Judge Rader's policy-oriented, flexible approach is endorsed by the U.S. Supreme Court,¹¹ the IP High Court's approach should be supported by Japan's national policy to become an IP-based nation.¹² As the U.S. Supreme Court did in *Bilski*, Japan's policymakers have already addressed the need to make the patent system ready for inventions in the Information Age.¹³ To secure protection for such inventions, the JPA was revised to clarify that the definition of statutory invention includes certain computer programs as patent-eligible subject matter.¹⁴ Reflecting the same needs and policies, the IP High Court has adopted a broad interpretation that aligns with Chief Judge Rader's approach to patent eligibility by giving courts flexibility to embrace unknown fields of inventions.

II. OBVIOUSNESS

A. *The United States*

Another facet of the U.S. patent system that benefits from Chief Judge Rader's extensive knowledge of foreign patent jurisprudence is obviousness. He used this knowledge both to avoid inappropriate uses of the obviousness analysis and to defend appropriate uses of it to ensure that patents do not get granted for unworthy inventions.

In *In re Deuel*,¹⁵ the Federal Circuit found nonobviousness with respect to a claim directed to cDNA molecules that encode a certain protein, heparin-binding growth factors. The prior art did not suggest the particular molecules, even if the general idea of the

¹¹ Peter Lee, *Antiformalism at the Federal Circuit: The Jurisprudence of Chief Judge Rader*, 7 WASH. J.L. TECH. & ARTS 405 (2012).

¹² Ichiro Nakayama & Toshiko Takenaka, *Will Intellectual Property Policy Save Japan from Recessions? Japan's Basic Intellectual Property Policy and Its Implementation Through the National Strategic Program*, 35 IIC 877 (2004).

¹³ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

¹⁴ JPA, art. 2, para. 3, item 1.

¹⁵ 51 F.3d 1552 (Fed. Cir. 1995).

claimed cDNA, its function, and its general chemical nature were obvious from the prior art.¹⁶ *Deuel* led to a special rule for DNA inventions: DNA is nonobvious over the prior art when the art includes (1) a disclosure of the amino acid sequence of the protein that the claimed DNA molecules encode and (2) a disclosure of a general method for isolating the claimed DNA.¹⁷ The nonobviousness standard under this special rule is more lenient than the inventive-step standard that the rest of the world follows and presents a significant obstacle to USPTO collaboration with other patent offices for examination of DNA inventions.¹⁸

Keenly aware of the USPTO's need to harmonize patentability standards, Chief Judge Rader commented on the serious problem caused by the lenient nonobviousness standard. In *In re Fisher*, the USPTO rejected claims that direct to expressed sequence tags ("ESTs") for encoding proteins and protein fragments in maize plants due to lack of specific utility.¹⁹ The Federal Circuit endorsed the USPTO's practice of requiring substantial and specific utility through its Utility Examination Guidelines. It cited *Brenner v. Manson*,²⁰ highlighting the function of the utility requirement for eliminating subject matter that does not deserve the grant of exclusive protection through a patent.²¹

Chief Judge Rader dissented because he found that the claimed express sequence tags have use as a research tool that provides a benefit to society, thus having required utility.²² He criticized the USPTO and the *Fisher* court's majority for failing to place the burden of challenging the utility asserted by the applicant on the USPTO. In his view, the lenient nonobviousness standard under *Deuel*'s special rule for DNA inventions forced the USPTO to adopt a heightened standard of utility for ESTs. According to Chief

¹⁶ *Id.* at 1558.

¹⁷ Thomas Isenbarger, *In re Kubin's Reinvigorated Nonobviousness Standard for DNA Patents*, 2009 WIS. L. REV. 1435, 1445 (2009).

¹⁸ Trilateral Project B3b, *Mutual Understanding in Search and Examination: Comparative Study on Biotechnology Patent Practices*, TRILATERAL, <http://www.trilateral.net/projects/biotechnology/mutual.pdf>.

¹⁹ 421 F.3d 1365 (Fed. Cir. 2005).

²⁰ 383 U.S. 519 (1966).

²¹ *Fisher*, 421 F.3d at 1371.

²² *Id.* at 1380 (Rader, J., dissenting).

Judge Rader, to make up for the marginalized function of the nonobviousness requirement, the USPTO needs to rely on the utility requirement for eliminating patent-unworthy DNA inventions:

In truth, I have some sympathy with the Patent Office's dilemma. The Office needs some tool to reject inventions that may advance the "useful arts" but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing "insubstantially" to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions.²³

In urging the Federal Circuit to overrule *Deuel*, Chief Judge Rader used comparative law to criticize the special rule: "Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used worldwide for such assessments (other than in the United States), namely inventive step or obviousness."²⁴

Because nonobviousness was not an issue on appeal in *Fisher*, Chief Judge Rader had to wait for an opportunity to address the problem in a case in which nonobviousness of DNA invention was squarely presented. He found such an opportunity in *In re Kubin*,²⁵ where the USPTO rejected DNA molecules for obviousness despite the lack of the prior art suggesting a particular structure of the molecules. Like *Deuel*, the prior art included a disclosure of the

²³ *Id.* at 1381-82 (citing *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995))_(Rader, J., dissenting).

²⁴ *Id.* at 1382.

²⁵ *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

particular amino acid sequence of the protein that the claimed DNA molecules encode and a disclosure of the method for isolating the DNA.

Instead of hearing the case en banc and overruling *Deuel* for upholding the USPTO's rejection, Chief Judge Rader relied on *KSR International Co. v. Teleflex, Inc.* to set aside *Deuel*.²⁶ He viewed the Federal Circuit's application of the nonobviousness standard in *Deuel* as inflexible, like the application in *KSR*, and thus inconsistent with Supreme Court precedent.²⁷ Relying on the Supreme Court's criticism of the Federal Circuit's application of the "obvious-to-try" doctrine (which cites *Deuel*), Chief Judge Rader concluded that "the Supreme Court in *KSR* unambiguously discredited that holding [in *Deuel*]." ²⁸

Nevertheless, he made clear that application of the "obvious-to-try" doctrine is proper if the doctrine is applied flexibly on a case-by-case basis by taking into account the number of choices.²⁹ The invention is nonobvious if the number of choices is large enough that a person having ordinary skill in the art of invention (PHOSITA) would not have arrived at a successful result by trying out these choices. In applying this flexible obvious-to-try test, Judge Rader concluded that a PHOSITA would have arrived at the claimed DNA molecules with a reasonable expectation of success because a disclosure of the protein motivated the PHOSITA to isolate the DNA and a method for isolating DNAs was available. As a result, Chief Judge Rader eliminated the special rule in *Deuel* and revitalized the function of the nonobviousness standard, which harmonized U.S. patentability with that of the rest of the world.

Although Chief Judge Rader is eager to admit mistakes made by his court in *KSR* and *Deuel*, he fiercely protects the court's practice in which the nonobviousness standard is properly applied. The nonobviousness standard functions to provide an objective measure to evaluate the contribution that the claimed subject matter has made with respect to the state of prior art and to

²⁶ *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

²⁷ *Kubin*, 561 F.3d at 1359.

²⁸ *Kubin*, 561 F.3d at 1358.

²⁹ *Id.*

eliminate subject matter that is unworthy of a patent grant.³⁰ To enhance this function, the Federal Circuit developed a practice of applying the teaching-motivation-suggestion test (TSM) in rejecting or invalidating claims for obviousness. The test requires an explicit or implicit teaching, suggestion, or motivation from the prior art, the nature of the problem, or the ordinary knowledge of those skilled to combine elements of the claimed invention disclosed in multiple prior art references.³¹ The test gives USPTO examiners and lower-court judges a framework to follow for obviousness assessments, which leads to objective and predictable results while protecting the assessments from hindsight.³² However, the TSM test was under fire when the Supreme Court agreed to review the Federal Circuit's well-established practice in response to criticisms from legal commentators that the test made it too difficult for the USPTO to reject claims directed to patent-unworthy subject matter.³³

Chief Judge Rader sought to preserve the TSM test by joining Judge Paul Redmond Michel, who was then chief judge, to issue an opinion in *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*³⁴ In *Dystar*, Judge Michel reviewed the Federal Circuit case law and explained that the TSM test was in fact applied very flexibly in the cases he had reviewed, observing that the court took into account common sense and common knowledge when finding suggestion.³⁵ The Supreme Court acknowledged Judge Michel's effort to clarify the court's practice and endorsed the application of the TSM test in nonobviousness assessment so long as the test is applied flexibly, as Judge Michel explained in *Dystar*.³⁶

³⁰ *Fisher*, 421 F.3d at 1382 (Rader, J., dissenting).

³¹ *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

³² Jennifer Nock & Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following KSR*, 20 FED. CIR. B.J. 369 (2011).

³³ FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8-15 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

³⁴ 464 F.3d 1356 (Fed. Cir. 2006).

³⁵ *Id.* at 1361 (Fed. Cir. 2006).

³⁶ *KSR*, 127 S. Ct. at 1743.

In *In re Translogic Technology, Inc.*,³⁷ Chief Judge Rader clarified the effect of *KSR* on the TSM test and used his knowledge of foreign patent doctrines to comment on how his court made a mistake in *KSR*:

On one level, *KSR* corrected a rather straightforward error. The error appears right before footnote 3 in this court's opinion:

In this case, the Asano patent does not address the same problem as the '565 patent. The objective of the '565 patent was to design a smaller, less complex, and less expensive electronic pedal assembly. The Asano patent, on the other hand, was directed at solving the 'constant ratio problem.'

Teleflex, Inc. v. KSR Int'l, Co., 119 Fed. Appx. 282, 288 (Fed. Cir. 2005). This passage overlooks the fundamental proposition that obvious variants of prior art references are themselves part of the public domain. In the context of *KSR*, the Asano teachings and its obvious variants were relevant prior art, even if that patent did address a different problem (the constant ratio problem).³⁸

Patent offices and courts in European and Asian countries developed the notion of obvious variants by enlarging the novelty standard to eliminate patent-unworthy inventions before a separate requirement of an inventive step was incorporated.³⁹ Under their current systems, some foreign courts take account of obvious equivalents in making the inventive step assessment.

Chief Judge Rader explained the Supreme Court's instruction to take account of common sense and customary knowledge by analogy to the enlarged novelty inquiry, which takes account of variations of items disclosed in the prior art if the variants are

³⁷ 504 F.3d 1249 (Fed. Cir. 2007).

³⁸ *Id.* at 1259 (internal quotations and citations omitted).

³⁹ WIPO International Bureau, Enlarged Concept of Novelty and the Prior Art Effect of Certain Applications under Draft Article 8(2) of the SPTL (2004) (draft), <http://www.wipo.int/scp/en/novelty/documents/5prov.pdf>.

obvious to a PHOSITA. He made clear that the TSM test is consistent with the Supreme Court's precedent as long as the test is applied flexibly by taking into account obvious variants. He further emphasized the benefit of the test, which is acknowledged by the Supreme Court: "In any event, as the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention, without unduly constraining the breadth of knowledge available to one of ordinary skill in the art during the obviousness analysis."⁴⁰

Because of Chief Judge Rader's clarification of the Court's instruction, the TSM test continues to play a vital role in nonobviousness assessment under the post-*KSR* Federal Circuit case law.⁴¹

B. Japan

In contrast to the Federal Circuit's TSM test, Japan's IP High Court's inventive step test came under fire for its stringent standard—legal commentators criticized it for often resulting in invalidity of patent filings due to lack of an inventive step.⁴² According to JPO Examination Guidelines, examiners can find a motivation to combine multiple references if the art of reference is analogous to the art of invention. This requires similarity of field of endeavor or the problem between the invention and the references.⁴³ This practice allows JPO examiners to find a

⁴⁰ *Translogic*, 504 F.3d at 1260

⁴¹ See, e.g., *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 ("This court has observed that teachings from prior art, suggestions beyond the literal teachings of those art references, or even motivations from the store of common knowledge of one of ordinary skill in the art field ("TSM")—flexibly viewed and applied—provide the sources of evidence that an ordinary skilled artisan might have found and combined at the time of the invention."); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008) ("[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis . . .").

⁴² Research Institute of Economy, Trade & Industry, IAA, Shigeo Takakura, *Review of the Recent Trend in Patent Litigation from the Viewpoint of Innovation*, http://www.rieti.go.jp/en/columns/a01_0242.html (last visited Apr. 13).

⁴³ Japan Patent Office, Examination Guidelines for Patent and Utility Model

motivation very easily and to reject claims for lack of an inventive step.

In comparison, under Federal Circuit case law, the USPTO can only cite a prior art reference from the analogous art.⁴⁴ In *In re Rouffet*, Chief Judge Rader made clear that a motivation to select and combine multiple references cannot be presumed simply because the references are analogous to the art of invention.⁴⁵ Even if the problem or field of endeavor of references is similar to those of the claimed invention, USPTO examiners must identify a teaching from the references giving rise to a motivation. USPTO examiners can rely on the nature of a problem: the PHOSITA's common knowledge to find a suggestion or motivation to combine references. If they rely on the knowledge of the PHOSITA, they must explain the specific understanding or principle within the knowledge that would motivate the PHOSITA to conceive a combination of elements as described in the claim. Without an explanation, it is likely that the examiners used hindsight to select the claimed combination,⁴⁶ as Chief Judge Rader correctly pointed out in *Monarch Knitting Machine Corp v. Sulzer Morat GmbH*.⁴⁷ Thus, USPTO examiners must explain a specific understanding if a suggestion comes from the nature of the problem because otherwise the USPTO and courts may formulate a problem in terms of the solution adopted by the inventor, thus relying improperly on the assistance of hindsight.

To respond to criticisms from the legal community, Japan's IP High Court adopted a test similar to the TSM test to guard against hindsight bias. In *Hitachi Kasei v. Commissioner of Japan Patent Office*,⁴⁸ the court reversed the JPO's rejection for lack of inventive step by using a general framework for making an assessment of an inventive step:

in Japan, pt. II, ch. 2, 2.5(2), http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/2_2.pdf.

⁴⁴ *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011); *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992).

⁴⁵ *In re Rouffet*, 149 F.3d at 1355.

⁴⁶ *Id.* at 1358.

⁴⁷ 139 F.3d 877 (Fed. Cir. 1998).

⁴⁸ Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.], January 28, 2009, Hanrei Jiho [Hanji] No. 2043, 117, Hanrei Taimuzu No. 1299, 272.

Whether a PHOSITA would have readily conceived the claimed invention on basis of the prior art must be decided by addressing a question whether a PHOSITA started from the prior art and would have readily arrived at the characterized elements (elements which are different from elements disclosed in prior art references). The characterized elements are those which are essential for solving the problem of the invention. It is necessary to define the characterized elements, and thus the technical problem to be solved by the invention for making an objective assessment of inventive step whether a PHOSITA would have readily conceived the invention. It is also necessary to avoid hindsight or illogical analysis throughout this assessment. To avoid hindsight, one should not formulate unconsciously “the technical problem” of the invention should in terms of “the solution” or “the result from the solution.”⁴⁹

The IP High Court further commented on a requirement of suggestion in the prior art:

To conclude that the claimed invention does not involve inventive step, it is not sufficient that the prior art indicates a possibility that a PHOSITA could have made attempts to arrive at the essential elements of the claimed invention. The prior art must include a suggestion that a PHOSITA would have arrived at the essential elements.⁵⁰

In *INAX v. Commissioner of Japan Patent Office*,⁵¹ the IP High Court refined this framework for a combination invention consisting of elements from multiple references by requiring a specific understanding, as Chief Judge Rader required in *Rouffet*.

⁴⁹ *Id.* Hanji at 126.

⁵⁰ *Id.*

⁵¹ Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] May. 27, 2010, Hei 21 (gyō-ke) 10361, Saikō Saibansho Saibanrei Jōhō [Saibanrei Jōhō], <http://www.courts.go.jp/hanrei/pdf/20100706093218.pdf>.

After remarking the relatively simple structure of the claimed invention, the court commented on a risk of hindsight particularly associated with combination inventions: “[I]t is easy to lead to a conclusion that a PHOSTA readily adopt the solution of the invention once the problem of the invention is made clear.”⁵² To avoid the risk, the court required JPO examiners to follow an analytical framework which consists of (1) a step of identifying the difference between the claimed invention and the prior art, and (2) a step of using a specific analytical process (understanding the significance of characterized elements in context of the technical problem and the solution for the problem while supplementing teachings from the prior art to determine whether a PHOSITA would have conceived the characterized elements). Unless the examiners can give an explanation for reaching their conclusion by following the specific analytical process, their conclusion of lack of an inventive step is improper. In *INAX*, the court found that the JPO did not make clear that it followed the analytical process because the JPO did not give an explanation for why a PHOSITA would have conceived the characterized elements by combining the references. Relying on this conclusion, the court revised the JPO’s decision.

In short, a test similar to the TSM is used by the IP High Court to make an objective assessment of an inventive step. By requiring an explanation with respect to a specific understanding or principle of how a PHOSITA would have reached the claimed invention, the IP High Court’s inventive-step assessment and the Federal Circuit’s nonobviousness assessment are protected from a risk of hindsight.

To maintain flexibility, both courts can take account of PHOSITA’s common sense and customary knowledge to explain the specific understanding or principle. This flexible application of the TSM test strikes a fine balance between two competing policies—providing a safeguard against hindsight and eliminating patent-unworthy inventions—as well as creates full harmony between the inventive step and nonobvious standards under Japanese and U.S. patent laws.

⁵² *Id.*

III. ENABLEMENT AND WRITTEN DESCRIPTION REQUIREMENT

A. *The United States*

Another critical facet of patent law is the enablement of the invention and the written description of the invention in the patent application. In *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*,⁵³ Chief Judge Rader was unsuccessful at convincing his colleagues to overrule *Regents of the University of California v. Eli Lilly & Co.*⁵⁴ and a series of precedents following *Lilly* in which the Federal Circuit, he believed, inappropriately applied the written description requirement to original claims. He argued that these cases made the written description requirement redundant with the enablement requirement if it applies to original claims in service of the same policy: policing the claim scope in contrast to the scope of disclosure.

If 35 U.S.C. § 112 is compared with the written description and enablement requirements under the European Patent Convention (EPC) and JPA, his arguments make sense. *Ariad* relates to claims directing a method for regulating gene expression by a transcription factor called NF-[K]B, which may cause harmful symptoms. The majority found that the disclosure of the allegedly infringed patent was invalid for lack of an adequate written description because the disclosure did not disclose a method for regulating the factor, and thus did not support that the inventors possessed the claimed method on the effective filing date.⁵⁵

In his dissenting opinion jointly authored with Judge Richard Linn, Chief Judge Rader argued that *Lilly* created a new written description doctrine that has no support in the patent statute and is inconsistent with the court's pre-*Lilly* precedent, in which the written description requirement functioned solely for policing the priority and thus applied to new claims that were not part of the original disclosure. He was particularly concerned with the impact

⁵³ 598 F.3d 1336 (Fed. Cir. 2010).

⁵⁴ 119 F.3d 1559 (Fed. Cir. 1997).

⁵⁵ *Id.* at 1568.

resulting from the new doctrine upon a fine balance provided in the U.S. Constitution:

The Constitution of the United States gives Congress, not the courts, the power to promote the progress of the useful arts by securing exclusive rights to inventors for limited times. Art. I, § 8, cl. 8. Yet this court proclaims itself the body responsible for achieving the “right balance” between upstream and downstream innovation. Ante at 28. The Patent Act, however, has already established the balance by requiring that a patent application contain “a written description of the invention, and of the manner and process of making and using it, *in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same.*” 35 U.S.C. § 112, ¶ 1 (emphasis added). In rejecting that statutory balance in favor of an undefined “written description” doctrine, this court ignores the problems of standardless decision making and serious conflicts with other areas of patent law.⁵⁶

Chief Judge Rader believes the new written description doctrine is redundant with the enablement requirement, serving the same policy of preventing inventors from claiming inventions that they did not invent, and thus failed to possess at the time of filing. In his view, a disclosure that is sufficient to meet the enablement requirement necessarily meets the requirement under the new doctrine for fully supporting a claim and showing the possession of the claimed invention by disclosing how to make and use the invention.⁵⁷ According to Judge Rader, the new doctrine is not only unnecessary but also harmful because the test of the new doctrine is not well defined and is therefore difficult for courts and applicants to apply.⁵⁸

Moreover, the new doctrine is in tension with an important rule

⁵⁶ *Ariad*, 598 F.3d at 1361 (Rader, J., dissenting).

⁵⁷ *Enzo*, 323 F.3d at 980-81.

⁵⁸ *Ariad*, 598 F.3d at 1364 (Rader, J., dissenting).

for claim interpretation. If claims are interpreted in light of the disclosure in the specification according to the rule that the en banc Federal Circuit adopted in *Phillips*, the claims should correspond with the scope of disclosure so that the disclosure fully supports the claims.⁵⁹ The new doctrine is also in tension with a rule that a patent owner of an improvement may infringe a patent of a basic invention on which the improvement is based.⁶⁰ It follows that an inventor of a basic invention is entitled to the scope covering any improvements that were nonobvious at the filing of the improvement patent and were not in the inventor's possession at the filing of the basic patent. Chief Judge Rader is concerned that the new doctrine invalidates claims that were issued to cover a genus, including species and improvements which can be separately patentable, and that were not in the inventor's possession at the filing date of the genus claim patent, effectively eliminating blocking patents.

B. Europe

European and Japanese judges face a similar challenge of distinguishing the enablement requirement and the written description requirement and finding a compromise between policies underlying the enablement-written description requirements and claim interpretation. The EPC codifies the enablement requirement and the written description in separate sections.⁶¹ Unlike the U.S. Patent Act, where both requirements are directed to the sufficiency of disclosure in the specification, the EPC's written description is directed to the sufficiency of claims. In contrast, the enablement requirement is directed to the sufficiency of disclosure in the specification. Another important difference between the U.S. Patent Act and the EPC is that a

⁵⁹ *Id.* at 1365.

⁶⁰ *Id.*

⁶¹ European Patent Convention (EPC) art. 83 requires patent application describing the invention in a manner sufficiently clear and complete for it to be carried out by a PHOSITA (the enablement requirement). EPC art. 84 requires the claims to be clear and concise and be supported by the description (the written-description requirement).

violation of the enablement requirement under the EPC is grounds for rejection during the pre-grant examination as well as grounds for revocation during the post-grant opposition, while the written description requirement is grounds for rejection during the pre-grant examination only.⁶² Thus, these requirements are not completely redundant.

EPC member states incorporated these requirements into their national patent laws as provided by the EPC. Thus, U.K. Patents Act 1977 (UKPA) copied the terms of these requirements under the EPC and provides sufficiency requirements for the disclosure and claims.⁶³ Reflecting the grounds for post grant opposition under the EPC, the UKPA provides only the enablement requirement as a ground for invalidating U.K. patents.⁶⁴ U.K. judges seem puzzled about why only one of the two requirements is a ground for invalidation. These requirements appear to serve the same policy and are seemingly redundant. Lord Oliver of U.K.'s highest court, the House of Lords, confirmed this view:

The Act does not contain any definition of the word “supported” but some assistance can be obtained from the provisions of section 14(5) which require the claim in an application to be “supported” by the description. That must, I think, involve the conclusion that if that which is contained in the description of the specification does not enable the claim to be established, it cannot be said to “support” it, for the Act can hardly have contemplated a complete application for a patent lacking some of the material necessary to sustain the claims made.⁶⁵

In *Biogen Inc v Medeva Plc*, Lord Hoffmann from U.K.'s

⁶² EPC art. 100.

⁶³ Patents Act 1977 (UKPA) § 14(3) requires the specification of an application to disclose the invention in a manner that is clear enough and complete enough for the invention to be performed by a PHOSITA (the enablement requirement). UKPA § 14(5)(c) requires the claim or claims to be supported by the description (the written-description requirement).

⁶⁴ UKPA § 72.

⁶⁵ *Asahi Kasei Kogyo KK's Application*, [1991] R.P.C. 485.

House of Lords agreed with Lord Oliver that the two requirements are redundant and therefore only one of them, the enablement requirement, is listed as a ground for invalidation under the UKPA.⁶⁶

In contrast, both requirements are grounds for invalidation under the U.S. Patent Act, despite Judge Rader's conclusion that these requirements are completely redundant. Enablement has a long history of serving the policy of policing the claim scope and establishing a predictable test. If the Federal Circuit finds it necessary to tighten the policy, the court should use the enablement requirement instead of the written description requirement.

European judges also agree with Judge Rader that there is a tension between the enablement-written description requirements and the claim interpretation and the blocking patent doctrines. In *Generics Limited v. H. Lundbeck A/S*,⁶⁷ Lord Walker further reinforced the view that the two requirements are redundant by citing *Exxon/Fuel Oils*, in which the enlarged board of the European Patent Office interpreted the enablement and written description provisions under the EPC:

Furthermore, Article 84 EPC also requires that the claims must be supported by the description, in other words it is the definition of the invention in the claims that needs support. In the Board's judgment, this requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the *technical contribution* to the art in order for it to be supported, or justified⁶⁸

Like Chief Judge Rader, Lord Walker has commented on the interaction between the enablement-written description requirements and the claim interpretation and blocking patent doctrines and tries to justify the scope of a patent that includes subject matter that is not sufficiently disclosed to enable a

⁶⁶ *Biogen Inc. v. Medeva Plc* [1997] R.P.C. 1.

⁶⁷ *Generics Ltd. v. H. Lundbeck A/S*, [2009] UKHL 12.

⁶⁸ T 0409/91, OJ EPO 1994, 653 ("Fuel oils/EXXON").

PHOSITA to carry out the subject matter without undue burden.⁶⁹ Relying on the above comment in *Exxon*, he concluded that claims and disclosure meet the enablement and written description requirements as long as the scope corresponds to the technical contribution. As described in *Generics*, in chemical and biotechnological fields, a claim frequently directs to an improvement of early compounds and DNAs that is covered by a claim in an earlier application, which Chief Judge Rader identified as the blocking conditions occurring in *Ariad*.⁷⁰

Lord Walker affirmed the Court of Appeals' finding that the claim for the (+) enantiomer of the known anti-depressant is valid. The scope of the claim should extend to any (+) enantiomer of the product regardless of the method for making the enantiomer without violating the enablement and written description requirement, even if many of these methods are not being enabled or supported by the disclosure of the patent. Because the court found that the technical contribution of the claimed invention is to produce the (+) enantiomer, the scope should not be limited by a method of making the enantiomer. In other words, under the UKPA, a blocking condition occurs with respect to species and improvements that the patentee did not enable or possess if the improvements are within the technical contribution.

In contrast, the *Ariad* majority's rigid application of the possession test may eliminate all blocking conditions, which will encourage knowledge exchange through cross-licensing between upstream and downstream patent owners and expose basic patents on genus chemical compounds and DNAs to the challenge of invalidity for a violation of the written description requirement.⁷¹ European judges would have agreed with Chief Judge Rader that an objective standard is necessary for upholding a blocking patent even if the disclosure does not support the inventor's possession of species and improvements which fall within the scope of the blocking patent.

⁶⁹ *Generics Ltd.* at ¶¶ 37-38.

⁷⁰ *Ariad*, 598 F.3d at 1335 (Rader, J., dissenting).

⁷¹ *Id.* at 1366 (Rader, J., dissenting).

C. Japan

Japanese judges would likely agree with Chief Judge Rader's assertion that the enablement and written description requirements should not be redundant in serving the same policy. The JPA's written description and enablement requirements mirror these requirements under the EPC.⁷² A major difference from the EPC is that the JPA makes clear that both requirements are grounds for revocation after patent issuance.⁷³ Thus, Lord Hoffmann's justification for having redundant requirements does not apply to the requirements under the JPA. Therefore, like Judge Rader, Japanese judges try to distinguish the enablement requirement from the written-description requirement.

In *Boehringer Ingelheim v. Commissioner of Japan Patent Office*,⁷⁴ the JPO rejected a claim that directed to the use of flibanserin to treat sexual disorders due to a failure to meet the written-description requirement. The JPO explained that the claim did not direct to an invention described in the specification because the disclosure did not include a description of the pharmacological data or its equivalent to establish the utility of the claimed compound for treating sexual disorders. On appeal, the IP High Court revised the JPO's decision for erroneously relying on the written-description requirement. The Court distinguished the policy underlying the written description requirement from that of the enablement requirement.

Article 36, Paragraph 4, Item 1, requires “a detailed explanation of the invention,” that includes the “necessary data to allow a person ordinarily skilled in the art who may try to understand the invention

⁷² JPA art. 36, para. 4 requires a detailed explanation of the invention, including a description of invention in a manner sufficiently clear and complete for the invention to be worked by a PHOSITA (the enablement requirement). JPA art. 36, para. 6, item 1 requires a claimed invention being included in the written description of the specification (the written description requirement).

⁷³ JPA art. 123, para. 1, item 4.

⁷⁴ Judgment of the IP High Court of Japan, Jan. 22, 2010, Hanrei Jiho [Hanji] No. 2073, 105. English translation of the case by the author is available in ADELMAN ET AL., GLOBAL ISSUES IN PATENT LAW 172 (2011).

to understand the relevant technical problems and how to solve them, and be able to understand the technical significance of the invention.” . . . The purpose of this provision is to create a patent system that grants a monopoly right for a set period of time to inventors who publically disclose their invention as compensation for that disclosure.

In contrast, Article 36, Paragraph 6, Item 1 requires that the “claim” include “a detailed description of the invention for which a patent is sought.” . . . If the scope of “claim” exceeds the scope of technical information described and disclosed in the “detailed explanation of the invention,” a grant of an exclusive right to such claims conflicts with the purpose of a patent system where an exclusive right is granted only to the extent of the scope of disclosure because a patent is granted as compensation for that disclosure. Thus, Article 36, Paragraph 6, Item 1 does not allow the inclusion of claims that exceed the scope of disclosure. For example, if the “embodiments” description only allows for a limited and narrow understanding of the technical aspects of the invention, while the “claims” description goes beyond the technical description encompassing a much wider technical scope, the claims will be in conflict with Article 36, Paragraph 6, Item 1, and should not be allowed.⁷⁵

In short, the enablement requirement relates to the policy for making sure that a PHOSITA understands the invention sufficiently to carry out the invention, whereas the written-description requirement relates to the policy of ensuring that the scope of exclusive right corresponds to the scope of disclosure. To reject a claim for a violation of the written-description requirement, the JPO must compare the scope of the claim and the scope of disclosure. Because the JPO’s rejection did not determine

⁷⁵ *Id.*; ADELMAN ET AL., *supra* note 74, at 172-73.

whether the claim scope exceeded the scope of disclosure, the IP High Court concluded that the JPO erroneously relied on the written-description requirement for rejecting the claim.

Japanese judges appear to share the same concern that Chief Judge Rader and Judge Linn indicated in *Ariad*: the claims at issue should have been rejected for lack of enablement instead of the written-description requirement.⁷⁶ Like *Boehringer Ingelheim*, the invalidity arguments in *Lilly* do not compare the claim scope with the scope of disclosure. Instead, the arguments focused on whether the disclosure in the *Ariad* patent includes a method of regulating the transcription factor.⁷⁷ By failing to include any method for performing the regulation, the disclosure does not provide enough information to make and use the claimed invention. Because any claim scope is enabled, the proper ground for invalidating the claim should be the enablement requirement. By allowing the written-description requirement to invalidate non-enabled claims, the majority marginalized the function of the enablement requirement as done by the JPO in *Boehringer Ingelheim*.

CONCLUSION

As the author of another article in this *festschrift* correctly points out, Chief Judge Rader uses a wide range of analytical methodologies and looks beyond traditional legal authorities in developing patent jurisprudence.⁷⁸ The comparative law method is one such methodology that he uses to interpret the statutory terms and develop new doctrines. The U.S. opinions, as well as the European and Japanese decisions influenced by Chief Judge Rader's work, reviewed in this Article are merely examples of his jurisprudence, highlighting his knowledge of foreign patent laws and his influence on European and Japanese judges. Through his openness to foreign patent law and eagerness to share his experiences with foreign judges, Chief Judge Rader stimulates academic discussions of U.S. patent jurisprudence in the context of

⁷⁶ *Ariad*, 598 F.3d at 1372 (Linn, J., dissenting).

⁷⁷ *Id.* at 1354.

⁷⁸ See Lee, *supra* note 8, at 418.

comparative law and greatly contributes to the harmonization of patent systems.