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## Foreword

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FOREWORD

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On the morning of July 22, 2011, many friends and admirers of Chief Judge Rader gathered at the University of Washington's High Technology Protection Summit to focus on the Chief Judge's many important opinions written during his more than 20 years on the Court of Appeals for the Federal Circuit. The morning consisted of two lengthy sessions following a keynote speech by a former student of mine, now a very experienced patent judge, the Honorable Marilyn L. Huff. The morning concluded with an address by the President of the University of Washington, Michael K. Young. Because President Young was instrumental in making the Chief Judge a permanent member of The George Washington University Law School faculty, his talk was the perfect capstone to the morning's events. Much of the afternoon was focused on Chief Judge Rader's influence on the patent laws of countries other than the United States.

Many of the speakers were kind enough to prepare formal remarks for the conference, and these papers form the basis for this *festschrift*. They include two excellent papers on the Chief Judge's influence on foreign patents law, one by Esther H. Lim, a former law clerk to Chief Judge Rader, dealing with Chinese patent law. The second, by Kaoru Kuroda and Eiji Katayama, discusses an important aspect of Japanese patent law. In addition, the papers include an article by Professor Robert W. Gomulkiewicz approving of the reasoning of an important contract law opinion written by the Chief Judge. However, I will focus this introduction

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on the papers that deal with the role of the Chief Judge in the development of American patent law doctrine.

I turn first to Professor Peter Lee's analysis of what he calls "Antiformalism." He finds evidence of Antiformalism in various decisions of the Chief Judge, but I suspect the record is more complicated because the Chief Judge believes in giving sound guidance to the public by means of easily understood rules so as to minimize legal costs. For example, is his opposition to the Federal Circuit's written description requirement for originally filed claims an example of Antiformalism or simply a questioning of why a new, vague, and unneeded requirement was added for originally filed claims? I believe it is the latter. Indeed, I do not believe any opinion of the Federal Circuit has answered his critique of using written description for originally filed claim as an added requirement alongside enablement.

Another general topic is the one treated by Judge Huff: the appropriate use of experts in patent cases. This is an area that the Chief Judge has covered extensively in a number of opinions including those written while sitting as a trial judge by designation. It fits in with his intense interest in claim construction and damage law. Judge Huff's article also gives the reader an inside view of how the jurisprudence of the Chief Judge has impacted the patent trial work of a distinguished district judge with a heavy patent docket.

Turning now to obviousness, the article by Professor Mark D. Janis is instructive in showing how obviousness considerations have impacted the Federal Circuit's utility and written description jurisprudence. The Chief Judge realized many years ago that *In re Deuel*<sup>1</sup> was wrongly decided and needed to be overturned. He said as much in his dissent in *In re Fisher*,<sup>2</sup> where he had the better argument, but politically the other panel members had no choice but to use the utility doctrine to invalidate the plainly obvious claims before the court. In addition, Professor Janis believes that the Federal Circuit has developed the written description doctrine for originally filed claims as another counterweight to *In re Deuel*.

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<sup>1</sup> 51 F.3d 1552 (Fed. Cir. 1995).

<sup>2</sup> 421 F.3d 1365 (Fed. Cir. 2005).

This is probably the case, although one that is hard to prove. In any event, it was the Chief Judge himself who finally laid *In re Deuel* to rest by invoking *KSR*<sup>3</sup> in *In re Kubin*.<sup>4</sup>

Professor Janis also reviews *In re Translogic*,<sup>5</sup> where the Chief Judge explained that any prior art reference and its obvious variations invalidates a claim that reads on any of its obvious variations. He carefully explained that this was the original error made by the Federal Circuit in *KSR*. However, the Chief Judge's role in *Dystar Textilfarben GmbH v. C.H. Patrick Co.*,<sup>6</sup> which issued shortly before the oral argument in *KSR*, was also extremely important in the modern development of obviousness jurisprudence. *Dystar* served as a vehicle for the Federal Circuit to explain to the Supreme Court how it should interpret both its own precedents and those of the Federal Circuit. The opinion was drafted by then-Chief Judge Paul Redmond Michel, with only Chief Judge Rader joining in the opinion. In explaining both lines of cases, *Dystar* made them look as good as possible. In essence, this was an amicus brief by Judges Michel and Rader that was carefully and wisely followed by Justice Kennedy. Indeed, while the Supreme Court is not a court that corrects errors, but rather deals with policy, after reading *Dystar* Justice Kennedy essentially left the policy set forth in its interpretation or rendition of the relevant case law alone and proceeded to fix the error made by the unpublished opinion in *KSR*. This may have saved the patent system from a train wreck.

Turning now to Professor Katherine White's review of a number of the Chief Judge's infringement decisions, I want to comment specifically on his concurring opinion in *Johnson & Johnston*.<sup>7</sup> I believe this is the best-reasoned opinion ever written anywhere in the world on the doctrine of equivalents. It actually explains when a sound patent system should permit non-textual infringement. Moreover, it was issued on March 28, 2002, and the

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<sup>3</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

<sup>4</sup> 561 F.3d 1351 (Fed. Cir. 2009).

<sup>5</sup> *In re Translogic Tech., Inc.*, 504 F.3d 1249 (Fed. Cir. 2007).

<sup>6</sup> 464 F.3d 1356 (Fed. Cir. 2006).

<sup>7</sup> *Johnson & Johnston Assoc. v. R.E. Service Co., Inc.*, 285 F.3d 1046 (Fed. Cir. 2002).

Supreme Court decided *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*<sup>8</sup> on May 28, 2002, precisely two months to the day later. Justice Kennedy's opinion tracks the Chief Judge's concurring opinion with respect to when a patentee may overcome a prosecution history estoppel except on one relatively small point. The Supreme Court would permit the use of the doctrine of equivalents with respect to a claim limitation even where an estoppel existed if adding the claim limitation was "tangential." In addition, of course, the Supreme Court following its own precedents divided the doctrine of equivalents question into two categories. In one, there is a prosecution history estoppel. In the other, there is no estoppel. The concurring opinion would make no such distinction, a distinction which makes little sense as I have explained elsewhere.<sup>9</sup> In short, had it followed the Chief Judge fully, the Court would not have erred by adding "tangential" and would have eliminated the unwise distinction based on prosecution history estoppel. But at least the Court went part way toward developing as the Chief Judge explained a sound doctrine of equivalents.

I now turn to Professor John M. Golden's paper on *Therasense*.<sup>10</sup> Although mentioned in his sixth footnote, Professor Golden might have made more of the powerful dissent of the Chief Judge in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*<sup>11</sup> That important case committed one of the great injustices of modern patent litigation. It involved a claim that a leading French scientist, Dr. Andre Uzan, intentionally and with the intent to deceive failed to disclose the dosage (60 mg) used to test the half-life of a prior art product when he compared it to the half-life of the claimed product, the very important drug Lovenox. Because ordinarily at pharmaceutically relevant doses first order chemical kinetics dictate that the half-life is independent of dosage, it is

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<sup>8</sup> 535 U.S. 722 (2002).

<sup>9</sup> Martin J. Adelman, *Patent Claiming in the United States: Central, Peripheral, or Mongrel?*, 1 IP THEORY 71 (May 8, 2012) <http://www.repository.law.indiana.edu/ipt/vol1/iss2/2>.

<sup>10</sup> *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc).

<sup>11</sup> 525 F.3d 1334 (Fed. Cir. 2008).

surely understandable that a leading scientist familiar with the art would not believe it important to reference the dosage when comparing the measured half-life of a pharmaceutical product at least at ordinary dosages. Just ask any doctor whether he or she believes there is a significant difference in half-life for any drugs used by the doctor at pharmaceutically relevant dosages.

Unfortunately, even though anyone with access to the Internet could learn about first-order kinetics, the dispute turned on measuring the half-life of Lovenox at different disclosed dosages and then measuring the half-life of a prior art composition at an undisclosed relatively high dosage for the purpose of showing that the half-life of Lovenox was *greater* than the half-life of the prior art formulation. From the prospective of the patent applicant, the lower the half-life of the prior art composition the better the test would look with respect to patentability. Since the withheld dose was on the high side, it was either irrelevant, the most likely situation, or it made the test appear slightly worse for the purposes of patentability as at some point increasing the dosage overloads the body and therefore causes a departure from first order kinetics, thereby increasing the measured half-life. However, given the variability of tests for half-life, some internal company data showed that the half-life at 40 mg when measured was greater than at 60 mg for the prior art product. A knowledgeable scientist would know that this result was most likely the result of experimental variation and not an underlying characteristic of the products and hence would not believe that the prior art dosage level was important.

In any event, the Chief Judge sensed that there was no reason for Dr. Uzan to deceive the USPTO and risk besmirching his distinguished reputation. As a result, he wrote a powerful opinion on intent. Of course, he was correct as I am sure that Dr. Uzan is wondering what is the matter with the education of Americans that they do not know about first-order kinetics in chemistry or that half-life is usually constant over the range of pharmaceutical doses. While the Federal Circuit did not correct the manifest injustice of its *Aventis Pharma* opinion by going en banc and reversing, it did try and make amends in *Star Scientific, Inc., v. R.J. Reynolds*

*Tobacco Co.*<sup>12</sup> and ultimately in *Therasense*. Unfortunately while a reading of the full opinion of the Board of Appeal in the European Patent Office discussing the prior art reference in *Therasense* shows that there was no conflict between the record in the USPTO and the proceedings in the USPTO, even after the en banc *Therasense* opinion, a true tour de force, Judge Alsup remained unmoved and found “inequitable conduct” under the new standards.<sup>13</sup> Whether *Therasense* will make the hoped for correction of inequitable conduct law is for the future. The implications raised by Judge Alsup’s opinion on remand and the Federal Circuit’s recent decision in *Aventis Pharma S.A. v. Hospira, Inc.* are not encouraging,

In sum, this *festschrift* covers only a small slice, but an important one, of the extensive work that the Chief Judge has done in his judicial career to date. We hope there will be much more significant judicial work in the future from him.

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<sup>12</sup> 537 F.3d 1357 (Fed. Cir. 2008).

<sup>13</sup> *Therasense, Inc. v. Becton, Dickinson & Co.*, No. C 04-02123 WHA, 2012 WL 1038715 (N.D. Cal. Mar. 27, 2012).