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PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD: LIBER AMICORUM JOSEPH STRAUS, edited by Wolrad Prinz zu Waldeck und Pyrmont, Martin J. Adelman, Robert Brauneis, Josef Drexl and Ralph Nack. Springer, 2009. 910 pp. Hardback $239.[1]

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On December 14th 2008, one of the world's most renowned patent scholars, Prof. Dr. Dres. h.c. Joseph Straus, celebrated his 70th birthday. Shortly thereafter, a great number of colleagues and friends gathered in his "academic home," the Max Planck Institute at Munich's Marstallplatz,[2] to congratulate and pay tribute to this "distinguished grandmaster of intellectual property law."[3]

One of his birthday presents was a colossal book honoring his lifelong dedication to intellectual property law and his widely recognized achievements, not only in his primarily patent law-related research and teaching, but also in creating the Munich Intellectual Property Law Centre and in leading, developing, and administering academic endeavors at the famous Max Planck Institute for Intellectual Property, Competition and Tax Law[4] with its tremendous library and research network. In over 900 pages this so-called *liber amicorum*[5] comprises 60 (!) articles written by friends, colleagues and pupils from more than 15 different countries in Asia, America, and Europe. The articles address a wide range of legal, economic and policy perspectives on various challenges related to the title of the book: PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED ECONOMY.

Starting with Rainer Moufang's portrayal of the fascinating life and career of Professor Straus and the leitmotivs of his work (pp.VII–XVII), which is followed by the table of contents and a brief description of the contributors (pp.XIX–XXX), the book sets out to address a remarkable variety of crucial

issues in the complex debates shaping today's technology-related intellectual property law. Besides dealing with topics that directly concern Professor Straus' primary research interest, i.e. international and comparative patent law with a special focus on the policy aspects raised by biotechnology and the interface of IPR with competition law, the book also features contributions discussing various procedural, multi-jurisdictional, and public policy aspects from a more general perspective.

The essays are thematically organized in 10 chapters, covering elemental questions of substantive patent and utility model law (Chapter 1); the delicate task of balancing exclusive patent rights with free market competition, addressing both system-immanent limitations on intellectual property protection (Chapter 2) and additional restrictions imposed by competition and antitrust laws (Chapter 3); technology specific problems concerning the adjustment of patent law to rapid developments in biotechnology and the pharmaceutical sector (Chapter 4); the legal protection of employee's inventions (Chapter 5); fundamental issues related to IPR procedure, enforcement, and liability (Chapter 6); the protection of technology against unfair competition (Chapter 7); multijurisdictional aspects of IP (Chapter 8); recent developments in national IP and competition legislation (Chapter 9); and public policies influencing the development of intellectual property law (Chapter 10). Finally, the book concludes with an additional chapter listing Prof. Straus' numerous and multifaceted publications (Chapter 11).

While many of the articles are kept reasonably short, the sheer scope and size of this book obviously presents a challenge to any reviewer bound to comply with page limitations. In order to do the book "some justice" one approach could be to briefly summarize and comment on each chapter and article.[6] Alternatively, the review could focus on a selection of articles covering specific issues that are of particular concern in current debates and that reflect the research focus of the celebrant. Considering the significant recent case-law developments and debates relating to the patentability of biotechnological and pharmaceutical inventions in both Europe and the U.S., as well as Professor Straus' main area of specialization, this review will follow the second approach and concentrate on the articles presented in Chapter 4 (Biotechnology, Pharmaceuticals and Patent Law).

Chapter 4 comprises seven articles on more than 100 pages (pp.197–304). It begins with an insightful analysis by the prominent IP Professor Martin J. Adelman from George Washington University Law School, who also happens to be a "good friend of many years" to Professor Straus and one of the book's co-editors.[7] In his paper titled, "The Inadequacies of the Section

271(e)(1) Jurisprudence of the United States Supreme Court" (pp.197–208), Adelman delivers a creative critique of recent U.S. case law developments concerning the applicability of the U.S. experimental use exemption with a particular focus on research tools.[8] He follows the unusual approach of constructing hypothetical cases based on the facts of *Roche v Bolar*[9] in order to demonstrate the effects of the decisions in *Eli Lilly v Medtronic*[10] and *Merck v Integra.*[11] Based on his convincing analysis Adelman arrives at the conclusion that the U.S. Supreme Court in *Merck v Integra* unfortunately "failed to do a clear, thoughtful and thorough job in this important case" (p.208). More specifically he criticizes the fact that the U.S, Supreme Court not only left unanswered the position of research tools with respect to Section 271(e)(1), but also refused to discuss the fairness of depriving the patent holder of all its benefits with respect to the genus claim (p.208).

Most stakeholders and academics would probably agree with Adelman that the Supreme Court decision was far too ambiguous and that further clarification is necessary to create reasonable legal certainty. The proper scope and application of experimental use and regulatory approval exceptions will therefore certainly continue to be vividly debated in the years to come. The controversy will be particularly fierce with regard to research tool patents. Ideally these exceptions should guarantee that patent laws aimed at providing incentives for technological innovation do not unduly restrict scientific research, innovative medical product development, and generic product competition.[12] In that respect, some judges and commentators will persist in highlighting the social harms that can result from a narrow interpretation of the exceptions, as demonstrated by the *Merck* decision, the (initial) invalidation of restrictively licensed stem-cell patents, and empirical studies suggesting that valid patents may—if the U.S. experimental use exception is narrowly construed—increasingly delay or restrict scientific research.[13] Others have argued that the ambiguous Supreme Court judgment may have gone far beyond what is necessary when limiting patent rights through research exemptions, thereby threatening the economic incentives provided by patents for the further development of innovative research technologies.[14] In that context it might also be worth adding that while experimental use and regulatory approval exceptions in the U.S. and the E.U. differ significantly in their history, scope, and application, these exceptions will presumably become even more essential to patent law and related regulatory policy in both Europe and the U.S.[15] It is therefore indispensable that any debates on the appropriate scope of research exemptions in both Europe and the U.S. also consider the impact of the generally more restrictive recent case law on patentable

subject matter, inventive step/non-obviousness, sufficient disclosure, and industrial application/utility. These cases have made it generally more difficult to receive patents on *immature* research results and undeveloped tools that are merely the objects (not subjects) of further research. This indicates that research exemptions should not be regarded as being the sole solution mechanism for tackling more or less significant problems.[16]

Related to this issue is also another possibility that—due to focus and page limitations—could not be sufficiently addressed in Adelman's paper: the introduction of a liability rule regime to facilitate access to research tools. That this seemingly wonderful idea might face specific difficulties in the biotechnological and pharmaceutical sector has been thoroughly discussed in Professor Straus' research. In addition to the potential difficulties associated with the determination of appropriate royalties in absence of a free market mechanism and potential conflicts with Articles 27, 30 and 31 of the TRIPS agreement, he reminds us that a liability rule regime would preclude exclusive licensing agreements. Unfortunately, however, such agreements still seem to be absolutely essential for some types of biotechnological research tools.[17] This is because an exclusive license guarantees exclusivity of research with the licensed invention, permitting the licensee a better prospect of recouping invested capital in the license itself.[18] Therefore, exclusive licensing may be particularly important for pharmaceutical research programs seeking to develop commercial applications for genetic inventions such as drug targets, rather than for research tool uses, considering the risks and costs associated with such development.[19] Although a potential liability regime definitely represents an interesting idea that deserves further consideration, sufficient capital investments and market returns may still depend upon the possibility of preventing such unlicensed research uses.[20] This clearly indicates that particularly with regard to biotechnological research tool inventions, the scope of research exceptions remains a tricky issue. The significance of further debate has also been emphasized by Professor Straus, who noted in 2004 that although the empirical studies available at that time had not demonstrated significant problems with development, licensing, and use of research tools, this may be more a function of ignorance of (or disdain for) the legal rules than of any recognition of what they are or should be.[21] All this adds particular weight to Adelman's disappointment with the jurisprudence of the U.S. Supreme Court. The next time the Supreme Court is confronted with similar questions it should indeed spend more time on these crucial issues. Although it seems to be impossible to deliver clear-cut answers, and the Supreme Court is generally prevented from giving judgment where there is no "live case or controversy" under the

Constitutional bar in Art. III, §2, cl. 1, the establishment of more coherent principles creating greater legal certainty would be most welcome. As recently as on August 31st, 2011 this was confirmed by the Federal Circuit decision in *Classen Immunotherapies, Inc. v. Biogen IDEC*,[22] where a split panel re-invigorated the debate as to the scope of the experimental use exception from infringement and the scope of the Hatch-Waxman "safe harbor" for drug-related testing under 35 USC §271(e)(1). The majority opinion and a strong dissent affirm the need to revisit this topic.

Professor Adelman's article is followed by Shoshana Berman's thoughtful consideration of the hazards of biotechnology for law and society in her paper "Legal and Moral Reflections on Modern Biotechnology in Use & Misuse" (pp.209-227). She begins with a description of international legislation addressing potential threats posed by dangerous or offensive uses of biotechnological inventions and highlights potential conflicts with the freedom of scientific research, and fundamental rights (pp.209-210). In that respect she delivers a thorough explanation of biotechnology's dual-use dilemma, i.e. in particular the blurred borders between peaceful and offensive uses of biotechnology, which lies at the heart of these conflicts. Moreover, Berman discusses unwanted risks stemming from the inherent unpredictability of biotechnology (pp.211-214). That point follows a random look at bio-safety and bio-security legislation, as well as case law from the U.S., the U.K. and the E.U. (pp.214-221). Her overview of recent judgments and legislation nicely demonstrates that in recent years serious efforts have been made by legislators and courts to control the use of and prevent the misuse of biological agents, although in a climate of uncertainties many conflicts and controversies still remain (pp.221-226). In her conclusion Berman regards the determination of an adequate balance in conflicts between human rights and national or international security to be one of the most difficult issues (p.226). While she considers the application of the "precautionary principle" to be necessary, she admonishes at the same time that "any normative framework for preventing, decreasing or minimizing any hostile use or misuses" must also respect the basic value of an "undisturbed continuation of scientific research" and the opportunity to publish scientific research results that do not unduly impede efforts to protect national security, as well as public health and safety. Berman then identifies the following questions as central (p.227):

1. How can scientific information on controversial issues be framed and communicated by the media, to be best absorbed and seriously received by policy makers, scientists and the general public?

2. What mechanisms can be applied for mediating between expert advice and warnings on risks and dangers and the common tendency of the individual to distance himself from threats and warnings?

3. What criteria shall be applied for resolving conflict of interest and controversies between the utilitarian-economic approach to scientific research, especially now in the field of new biotechnology and other approaches such as political, ethical, moral; social or religious?

Having dealt with these issues both as a judge and lecturer, Berman finally notes that there is a "growing gap between scientific expertise and judicial knowledge." Since "no man is an island"[23] she concludes that there is a clear demand for cross-ventilation between all the relevant disciplines, which "Professor Straus is practicing in his daily chores" (p.227). While Berman concentrates on issues relating to misuses of biotechnology in warfare and the potentially extreme dangers posed by insufficiently controlled peaceful uses of viruses and bacteria, many of her findings will certainly also have to be discussed in (perhaps only seemingly) less dramatic settings. One could, for example, think about similar problems related to novel scientific insights in epigenetics and nanotechnology. Recent research demonstrates that these rapidly developing disciplines are blurring the frontiers of science and present particular legal, social, ethical, and scientific challenges.[24] Once again, law is having difficulty in keeping up with these rapid technological developments and finding answers to the questions identified by Berman will be essential even in these areas.

The third paper in Chapter 4 with the title "Biotechnological Patenting and Innovation" (pp.229-241) is authored by Michael Blakeney. It discusses a variety of issues that are of particular concern when discussing patents on biotechnological inventions. In combining his patent law analysis with scientific facts and economic insights, such as Machlup's views on the interplay of patenting and innovation, he addresses some crucial topics, including overly broad claims and actual or potential problems that these might create for biotechnological research (pp.230-233), patents on research tools (p.232), licensing issues (p.233), patent thickets (pp.233-236) and patent pools (pp.236-238). Finally, Blakeney makes some remarkable comments on the interplay of patents with competition law (which could as well have made his paper part of Chapter 3). He examines in particular the impact of competition law upon biotechnological licensing (p.238), as well as on patent pools and cross licensing (pp.238-240). In his conclusion he refers to Professor Straus' earlier realization that patents not only play a significant role as competitive tools in various biotechnology contexts, but

also for preserving the value in biodiversity and in distributing benefits to source communities (p.241). Blakeney finally notes that "in both of these areas further research is necessary to examine the extent to which competition policy can preserve the benefits which every patenting should secure," a finding which corresponds well with the increased scrutiny of patent law by competition/antitrust authorities and courts in both Europe and the U.S.

Somewhat related to these conclusions is the subsequent article by Tanuja Garde entitled "Circumventing the Debate over State Policy and Property Rights: Section 3(d) of the Indian Patents Act Law" (pp.243-254). Garde analyzes the historical and constitutional background to §3(d) of the Indian Patents Act. This is an extraordinarily interesting provision, since it was introduced to prevent so-called "evergreening" strategies typically employed by the pharmaceutical industry. More specifically §3(d) provides that the following does not constitute an invention under Indian patent law:

> "[t]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere new use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."[25]

Besides explaining the Indian debates on the redistribution of real property and the very critical post-independence evaluation of the patent system, which led to fierce opposition during India's accession to the WTO/TRIPS and to the introduction of this (in)famous provision (pp.243-250), Garde also examines its actual impact on selected decisions relating to patents and patent applications by the pharmaceutical giant Novartis (pp.250-253). She concludes that §3(d) effectively limits "the ability to obtain property rights in incremental pharmaceutical innovation, where currently the bulk of pharmaceutical research and developments occurs, including medicines that may be more effective in tropical climates, such as heat stable forms, but not necessarily more efficacious" (p.254). She also observes that by denying any patents on such inventions, §3(d) "circumvents a battle over determination of just compensation or equitable remuneration, as required when issuing a compulsory license." Finally, she remarks that this calls for an examination of whether §3(d) might actually violate TRIPS, and in particular the anti-discrimination clause in Article 27 TRIPS (p.254). Considering Novartis' continuing challenges to Section 3(d) at the Indian Supreme Court and recognizing that so-called "evergreening" strategies are also fiercely debated under U.S. and European patent, competition, and

pharmaceutical regulatory law, Garde's analysis provides valuable input. Since India is currently undertaking great efforts to strengthen its domestic generic industry, a similar examination of the Indian regime on data and market exclusivities would probably lead to equally interesting results.

Next, the paper "Medical Use Claims: EPC 2000 and its Impact on Prosecution and Enforcement" (pp.255-274) by Hans-Rainer Jaenichen, Jürgen Meier, and Niels Hölder analyzes the significance of the 2000 revision of the European Patent Convention ("EPC 2000") and its "new" Articles 54(4) and (5) EPC[26] for the prosecution and enforcement of medical use claims. The authors start by highlighting the general relevance of patents as incentives in the pharmaceutical sector, describing the increasing costs of (bio-) pharmaceutical R&D, the high proportion of pharmacologically interesting compounds that fail before reaching the clinical trial phase, and the comparatively low success rate of those compounds that actually make it to the clinical trial stage. The authors then explain the particular concept and significance of compound patents, first medical use patents and patents for second (and subsequent) medical uses. After mentioning several examples of conventional small molecule pharmaceuticals and large-molecule biologics that were successfully protected by compound protection, the authors point out that, in some cases, the identification of first, second and further medical uses may actually provide the first prospects for profit (pp.255-256). Besides providing examples of such inventions, which enjoy simplified purpose-limited claim protection under the EPC 2000, the authors also refer to the necessity for additional forms of protection that may complement patent protection, such as Supplementary Protection Certificates, data protection/market exclusivity, and orphan drug and pediatric regulations (p.256). Next, they deliver a brief description of the European Patent System, followed by a more detailed analysis of how the European Patent Office ("EPO") and national systems, such as the U.K. and Germany, deal with patents covering various medical use-claims of known compounds. In that respect the authors refer to many different patent scenarios involving a variety of medical-use categories, such as novel target populations, routes of administration, claimed additional technical effects or treatment regimes. They describe how these categories are addressed by European courts in both patent prosecution and enforcement litigation, including various direct and indirect infringement situations (pp.257-274). The authors also note the often stricter approach of national courts in considering validity and infringement, for example, in cases where the claim is essentially directed to an unpatentable method of medical treatment. They finally conclude that while the EPC 2000 has basically left the legal situation for prosecuting and

enforcing purpose-limited claims covering the first medical use unchanged,[27] the new Article 54(5) EPC relating to second medical uses has now incorporated into the EPC what has been developed in many years by the EPO's jurisprudence.

Although it is generally believed that the purpose-limited compound claims that are now available for second medical uses under Article 54(5) EPC 2000 have substantially the same effect as the previously used Swiss-type claims, the authors identify two main advantages (p.274). First, the new regime provides, in combination with Article 138 EPC 2000, legal certainty since national courts will now have to respect the patentability of second medical use inventions (which might also encompass cleverly phrased claims on treatment regimes and in particular claims that make the treatment regime a feature of the composition itself). Second, since a purpose-limited second medical use claim under Article 54(5) EPC 2000 covers—in contrast to the previously available Swiss-type claims—off-label uses, the new format is likely to increase the protection of such specific uses and, under the principles of indirect infringement, "offers and deliveries of non-customized products suitable and intended/used therefore" (p.274). Besides clarifying advantages that the EPC 2000 entails for patentees during patent prosecution and litigation, another of the authors' achievements lies within their interesting explanation of the various categories of second medical use claims that patent offices are typically confronted with. Readers who are not so well-acquainted with pharmaceutical patenting, the EPC and the case law of the EPO, will be astonished by the great number and variety of purpose-limited patents for second medical uses of known pharmaceutical compounds already granted by the EPO. On the other hand, those more familiar with (bio-) pharmaceutical R&D will find confirmation. The increasing relevance of medical use claims clearly reflects the current paradigm shift in pharmaceutical R&D. Encouraged by rapid scientific advances in molecular biology and an enhanced understanding of cellular pathway mechanisms, epigenetics and the interplay of genes and proteins, the industry is increasingly focusing on the development of personalized medicines, novel applications of known small molecule drugs, as well as cutting edge large-molecule biologics or biosimilars. This will create a variety of challenges in several legal areas, including patent related law and the legal framework for regulatory exclusivity periods. With respect to patent law, the scope of the aforementioned exclusions from patentability of medical methods, which is expressly permitted under Art. 27 TRIPS, is one of the most discussed issues. The debate is particularly intense in the case of diagnostic methods.

That specific topic is addressed in the following paper on the "Purpose and Limits of the Exclusion from Patentability of Medical Methods, Especially Diagnostic Methods" by Rudolf Kraβer (pp.275-288). In providing an initial overview on the genesis and substance of the excluding provisions in the EPC (including references to German case law and legislation on diagnostic methods and second medical uses), the author describes the systematically correct "delinking" of considerations related to the "industrial applicability" requirement from the patent ban on medical procedures under the EPC 2000 (pp.275-278). Next, the author considers the various rationales for excluding medical procedures from patentability (pp.279-281) and describes case-law developments primarily from Germany and the EPO's Technical Boards of Appeal (TBA) and Enlarged Board of Appeal (EBA), demonstrating that the general European bar to the patentability of medical methods is still very restrictively interpreted as applied to diagnostic methods (pp.281-288). In his concluding remarks Kraβer generally welcomes the more recent case law from the EPO as abolishing false interpretations to be found in earlier case law and establishing proper principles for a variety of problems, such as the question of when a diagnostic method is to be considered as "practiced on a human or animal body" and who should be considered as carrying out such methods. However, he also notes flaws in the EBA's definition of the term "diagnostic method." Quite correctly he points out that by focusing on the deductive activities of medical practitioners, the EBA failed "to consider the possibility that a restraint can take place during the data collection phase that a doctor needs as the basis for his conclusion." According to Kraβer, this drains the established principles "of any practical relevance." In that respect the authors also admonishes that the application of Article 84 EPC (on the claim clarity) does not constitute an appropriate legal means "to resuscitate the exclusion to the extent called for by the spirit of the law."

Professor Kraβer's analysis clearly demonstrates that Europe is currently going through its own national, international, and supranational debates on patentable subject matter. Due to the particular European legal framework the debate is characterized by specific dynamics raising some questions that are rather unique to the European setting. This was confirmed in a series of seminal decisions by the EPO and the Court of Justice of the European Union (CJEU) both pre-[28] and post-dating[29] the author's analysis. However, as illustrated by Kraβer's data collection example, recent European developments also address several issues that are very similar to those currently discussed in the U.S. in the aftermath of the U.S. Supreme Court decision in *Bilski v. Kappos*.[30] Thus, comparative studies of these developments are now more interesting than ever. Besides the impact of the

new case-law on patentability exclusions relating to abstract ideas and computer programs (which was the main focus of *Bilski*), the patentability of medical uses, dosage regimes, procedures and diagnostic methods seems in light of the above described paradigm shift in (bio)-pharmaceutical R & D to be the most relevant field for comparative studies. Particularly interesting for this technology is a series of Federal Circuit decisions that were influenced by *Bilski*. One of these cases, i.e. *Prometheus v. Mayo*,[31] will soon be considered by the U.S. Supreme Court, which will provide further clarification for biotechnological and pharmaceutical sciences. Other cases might follow. In that respect, Kraβer's discussion provides valuable comparative input. Furthermore, it will be interesting to explore how the U.S. courts decide upon the closely related question concerning the appropriate scope of protection to be conferred to such inventions. As for the U.S., the post *Bilski* CAFC decisions in *Prometheus v. Mayo* and *AMP v. USPTO*[32] indicate that this question is particularly controversial in the case of pharmaceuticals and DNA- or protein-related inventions. The appropriate scope of protection for such inventions is also heavily debated in Europe and has led to completely divergent national interpretations of Directive 98/44/EC (E.U. Biotech Directive). In some national European patent systems, such as Sweden, Denmark, and the U.K., as well as at the EPO and the USPTO, full product protection seems—at least in principle and despite recent challenges—still to be available for qualified DNA- and protein-related inventions. In contrast, however, a number of European states, such as Italy, France, and Germany, have enacted legislation that effectively limits the scope of protection conferred on such inventions. Some national rules even oblige the patent applicant to include the claimed function of complete or partial human DNA (or even protein) sequences with a structure that is concordant to naturally occurring sequences directly into the patent claims, thereby automatically limiting the scope of protection of the patent to that particular function. Obviously, this special treatment of (human) DNA-related technology raises fundamental questions as to the proper interpretation of i.a. Article 27(1) TRIPS. Moreover, this legislative diversity stands in stark contrast to the harmonization goal of E.U. Directives. This has stimulated a widespread debate on the proper interpretation of the E.U. Biotech Directive and it was clear that guidance from the CJEU was required.[33] In July 2010 some of these question were answered by the CJEU in C-428/08, *Monsanto Technology LLC, v. Cefetra BV*, where the CJEU held the scope of product claims on DNA sequences in soya beans to be limited to their function as claimed and not applicable to any other product, such as soya meal used for nutrition, in which the sequences did not fulfill their specific function.[34]

Monsanto was decided after the publication of the book and arguably leaves some issues unresolved due to the specific factual circumstances underlying the case and the specific focus of the decision.[35] Interestingly, some of the questions addressed in this case are discussed by the last article in Chapter 4 titled "Special Legislation for Genetic Inventions—A Violation of Article 27(1) TRIPS?" (pp. 289-304). It was written by another of the editors, Wolrad Prinz zu Waldeck und Pyrmont, who examines how far legal rules that exclude patent protection or limit its effects in biotechnology comply with the anti-discrimination clause of Article 27(1) TRIPS. He begins by explaining developments in the biotechnological sector (p.290) and the hotly contested debates over broad patents on multifunctional biotechnological products that resulted in the aforementioned national legal responses (p.291). This is followed by a description of various national legislation that introduced restrictive infringement rights and claim limitation for certain DNA- or protein-related inventions into French, German, Italian, and Swiss patent laws in order to mitigate the envisaged negative effects of overly broad biotechnology patents (pp.291-293). Next, the author scrutinizes the definition of "discrimination" (pp.293-295) and the extent of permissible "differential" treatment under TRIPS (pp.295-303). He also discusses various policy aspects and rationales against permitting sectoral derogation from general provisions. Prinz zu Waldeck und Pyrmont concludes that "restricting the scope of gene patents to the disclosed purpose while maintaining the principle of absolute product protection for all other technical fields," such as in German, French, Italian, and Swiss patent law, "undoubtedly violates Article 27(1)" TRIPs and adds that even a broad interpretation of TRIPS cannot justify such legislation (p.304). From a practical point of view, the author further warns that "using the fact that the object of the invention is a "gene" as the basis for a legal categorization does not appear very helpful" due to the increasingly disputed and "fuzzy" definition of a gene.[36] Finally, he observes that such technology-specific (patent) legislation "is backwards oriented and bears the danger of becoming obsolete or ill-fitting with the progress of technology" (p.304).

While other commentators,[37] as well as the AG and the CJEU in *Monsanto*, have taken a different view, it should perhaps be noted that an interesting "middle position" was expressed by Professor Straus in 2003. He differentiated between gene sequences whose isolation required an inventive activity and those situations where the examination of the relevant state of technology reveals that the inventive merit "merely" lies in the clarification of the function of a newly discovered gene that had been isolated by application of routine techniques.[38] In the first situation, which

due to scientific developments has become very rare, full product protection might perhaps be justified, whereas the latter situation would arguably only justify purpose limited product protection. This is certainly an appealing idea. However, today it seems as if these discussions have indeed lost some of their practical relevance. There are basically four related main reasons for this notion: 1) most of the sometimes overly broad patents that were granted in the early days of the biotechnological revolution have now expired or are about to expire; 2) recent advances in synthetic biology have made it possible to construct genes or proteins that do not necessarily correspond to natural sequences and to influence their specific functions; 3) due to legislative and procedural changes it has generally become easier to attack overly broad product claims during patent litigation; and 4) as for patent prosecution, rapid scientific developments and the strict application of basic patentability requirements, such as inventive step and sufficient disclosure, have made it more difficult to receive full product patents on naturally occurring DNA and protein sequences. These are often already disclosed or have been isolated by routine methods. Moreover, an increasing number of naturally occurring functions have been identified or can be predicted by the application of modern technology (although it may be argued that these functions and their interplay have proven to be much more complex than previously contemplated). As a consequence, modern science is focusing on truly inventive applications of gene and protein technology which are often more limited in scope and therefore do not raise the same problems with regard to full product protection. Accordingly, both the author's interesting contribution and the conflicting CJEU judgment in *Monsanto* illustrate very nicely that legal reactions once more appear to have difficulties in keeping up with scientific developments. Be that as it may, emerging technologies will certainly pose similar questions in the future and the general significance of this discussion for the development of legal doctrines and principles remains undisputed. Prinz zu Waldeck und Pyrmont is therefore generally correct in pointing out that legislators and policy makers should be extremely cautious before introducing technology-specific patent legislation. In that regard it should particularly be recognized that, while problems with overly broad product patents appeared to be most severe ten years ago, the strict application of patentability requirements and further solution mechanisms seem now to have taken effect. Hopefully, this will alleviate some of the initial concerns about impeding effects on biomedical research, which – as also pointed out by the author (p.300)—have often not been validated.[39] Last but not least, it is important to realize that the early grant of (from a hindsight perspective) perhaps overly broad patents has been an important factor in stimulating the biotechnological revolution.[40]

Since this review only addresses a selection from among the contributions, it should be added that most of the remaining authors have written equally interesting essays on equally exciting topics. It can further be concluded that the editors, most of whom also contributed papers, have generally succeeded in the difficult task of structuring, systemizing, and arranging the different parts. This has resulted in a very readable book. But are there any flaws?

Considering the numerous useful case law citations, as well as the size and scope of the book, a minor imperfection may perhaps be found in the general absence of any cross-references, indexes or tables of cases. Those deeply engaged in legal research might realize this ellipsis as it renders serious study of this book a little more inconvenient. Yet, it should also be born in mind that this might have delayed the completion of the book and timing is obviously a crucial factor for such a special birthday present. These minor slips are therefore excusable, although they should perhaps be remedied by a supplement satisfying even the most pedantic, nit-picking critics.

Leaving aside these subtleties, it can be assumed that Professor Straus has studied his birthday present with great pleasure and interest. While he might not fully agree with some of the findings and proposals presented in it, the overall theme of the book indeed "reflects Joseph Straus' pronounced interest in the patent system and the challenges that it faces both on a national and international level."[41] There is no doubt that the editors and authors have compiled a magnificent book and a worthy tribute to honor the career of a truly exceptional patent scholar. For years to come, this immense collection of essays will provide stimulation and inspiration to many academics and their students. Consequently, this book is also of great interest to stakeholders, policy makers, judges, and practitioners.

This is an extraordinarily interesting book well suited to honor the outstanding career of an extraordinary scholar in an extraordinarily exciting era for intellectual property and competition law. It ought to be found in any library that has reserved space for IP-related literature.

ENDNOTES

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[1] This review does not consider legal changes that have occurred after August, 2011.

[2] The seat of the Max Planck Institute for Intellectual Property & Competition Law.

[3] Rainer Moufang, in Wolrad Prinz zu Waldeck et al. (eds.), PATENTS AND TECHNOLOGICAL PROGRESS IN A GLOBALIZED WORLD: LIBER AMICORUM JOSEPH STRAUS (Springer, 2009), at VII.

[4] Since 1 January 2011 the MPI for Intellectual Property, Competition and Tax Law has been split to form the MPI for Intellectual Property and Competition Law, and the MPI for Tax Law and Public Finance. At the same time these Institutes, along with the MPI for Foreign and International Social Law, have joined together to form the Munich Max Planck Campus for Legal and Economic Research.

[5] The concept of a so-called *liber amicorum* (lat: book of friends) stems from a respected tradition of civil law countries to pay tribute to respected legal scholars. A typical *liber amicorum* is comprised of a collection of essays that have been written by close friends, colleagues and pupils (such as doctoral students). It is also often referred to as mélange (Fr.), Festschrift (Ger.), or festskrift (Sw./Dan./Norw).

[6] This approach has been applied by Alison Firth, Book Review–Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus, 32 E.I.P.R. 4, 184-189 (2010) (providing a comprehensive review covering virtually each of the book's 60 articles).

[7] In the introduction to his paper, Adelman mentions that as a Marshall Coyne Visiting Professor of International Law at George Washington University Law School, he and Professor Straus have co-taught several chemistry and biotechnology related patent law courses. Professor Straus and Adelman have also collaborated in establishing Professor Straus' "baby," the Munich Intellectual Property Law Centre.

[8] This paper would thus also have fit into Chapter 2.

[9] Roche Products v Bolar Pharmaceuticals, 733 F. 2d 858 (Fed. Cir. 1984).

[10] Eli Lily v Medtronic. 5 U.S.P.Q. 2d 1760 (E.D. Pa. 1987).

[11] Merck v Integra Life Sciences, 545 U.S. 193 (2005).

[12] Cf. the abstract of Joshua D. Sarnoff and Henrik Holzapfel, A Cross-Atlantic Dialog on Experimental Use and Research Tools, ExpressO (2007),

available at http://works.bepress.com/joshua_sarnoff/1/ (last visit 10 May, 2011).

[13] Id.

[14] See Wolrad Prinz zu Waldeck und Pyrmont, Research Tool Patents after Integra v. Merck–Have They Reached a Safe Harbor?, 14 Mich. Telecomm. & Tech. L. Rev. 2, pp. 367-446 (2008), available at SSRN: http://ssrn.com/abstract=1132025 (concluding after an examination of U.S. and European statutory law and practice, obligations imposed by international treaties, and the rationale of the patent system, that "to preserve the necessary incentives for the creation of research tools—the next judicial decision should clarify that neither of the two exemptions from infringement extends to the use of research tools in experiments. Allowing access to research tools under any of the exemptions—though arguably having a positive short term effect—would endanger the development of sufficient (and needed) innovative research technologies which may have a greater negative impact on the pace of biotechnological research than occasional lack of access to a needed resource.").

[15] Cf. Henrik Holzapfel and Joshua D. Sarnoff, A Cross-Atlantic Dialog on Experimental Use and Research Tools, 48 IDEA 2, 224 (2008) available at http://law.unh.edu/assets/pdf/idea-vol48-no2-holzapfel-sarnoff.pdf (last visit 10 May, 2011).

[16] Concerning the U.S. utility requirement, the CAFC has made this explicit in In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005). Similar case-law can be found in Europe. For a comparative overview, see Timo Minssen, När anses en bioteknologisk uppfinning vara komplett och praktisk användbar– Part I–USA, NIR 201-60 (2008), & Part II–Europe, NIR, 339-387 (2008) (in Swedish).

[17] Joseph Straus et al., Genetic Inventions and Patent Law: An Empirical Survey of Selected German R&D Fustitutina, 22 (Verlag, 2004).

[18] Cf. Henrik Holzapfel and Joshua D. Sarnoff, supra note 15 at 222-223.

[19] Id.

[20] Id.

[21] Id. at 224 (referring to Straus et al., supra note 17, at 25; John P. Walsh et al., Working Through the Patent Problem, 299 SCIENCE 1021 (2003)).

[22] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

[23] Citing John Donne, Mediations XVII.

[24] A good overview about current research and unsolved questions concerning the "epigenetic or histone code" is provided by Bryan M. Turner, Defining an epigenetic code, 9 Nature Cell Biology 2-6 (2007), and id. Simplifying a complex code, 15 Nature Structural & Molecular Biology 542-544 (2008); Cf. M. Rothstein et al., The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics, 19 Health Matrix 1 (2009); M. Rothstein et al., Ethical Implications of Epigenetics Research, 10 Nature Reviews Genetics, 224 (2009); Antonei B. Csoka & Moshe Szyf, Epigenetic side-effects of common pharmaceuticals: A potential new field in medicine and pharmacology, 73 Medical Hypotheses 5 (2009), at 770-780.

[25] Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

[26] Under the EPC 1973 first medical use claims were protectable under Article 54(5) EPC 1973. Second medical use claims have previously been accepted by the EPO as so-called "Swiss-type" claims. The EPC 2000 editorially amended Article 54(5) EPC 1973 to become Article 54(4). Moreover, the EPC 2000 introduced the new Article 54(5) EPC 2000, which provides for the purpose-limited protection of second and further medical use claims. As a consequence, the so-called "Swiss-type" claims became obsolete.

[27] Adding that "the only, though substantial, legal difference to a purpose-limited compound claim for a second medical use as now admissible is that the first medical use claim is not limited to a specific indication by definition, which is why an infringement action requires less detailed evidence. In all other respects the enforcement is similar."

[28] See G 1/04, OJ 5/2006, 334 (diagnostic methods). Note that due to the different legal framework, the European discussion raises sometimes comparable but also slightly different issues than in the U.S.; cf. Eddy D. Ventose, Making Sense of the Enlarged Board of Appeal in

Cygnus/Diagnostic Method, EIPR 145-50 (2008); Sven J.R. Bostyn, No Contact with the Human Body Please! Patentability of Diagnostic Method Inventions after G01/04, EIPR 238-44 (2007).

[29] Cf. Recent EPO Enlarged Board of Appeal decisions on Art. 52, 53 & 54 EPC in G 0003/08 (May 2, 2010-computer implemented inventions); G 2/08 (February 19, 2010–dosage regime); G 1/07 (February 15, 2010-method for treatment by surgery); G 2/06 (November 25, 2008-embryonic stem cells).

[30] Bilski v. Kappos 130 S. Ct. 3218. Cf. Timo Minssen and Robert M. Schwarz, US Patent Eligibility in the Wake of Bilski v. Kappos: "Business as Usual" in an Age of New Technologies?, 30 Biotech. L. Rep. 1, 3-56 (2011).

[31] The patent challenger sought review of the recent CAFC decision in Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 628 F.3d 1347 (Fed. Cir. 2010)(Lourie, J.). In 2011, the Supreme Court granted certiorari, see: In Mayo Collaborative Services v. Prometheus Laboratories, Inc., Supreme Court No. 10-1150. Cf. the prior decisions in Mayo Collaborative Services v. Prometheus Laboratories, Inc., __ U.S. __ (2010)(per curiam), grant of certiorari, vacation and remand from the Supreme Court in light of Bilski v. Kappos, 130 S.Ct. 3218 (2010), prior opinion, 581 F.3d 1336 (Fed. Cir. 2009) (Lourie, J.), where the Federal Court once again reversed the District Court to rule Prometheus' methods to be patent-eligible subject matter under 35 USC §101.

[32] On July, 29th 2011 the CAFC rendered a split decision in the "Myriad-case," which might pave the way to a Supreme Court showdown, see: Association for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011)(Lourie, J.). The majority held that claims on "isolated DNA" and "cell-based drug screening methods" are patent-eligible under 35 USC §101, but that the "comparing" or "analyzing" method claims are not. Cf. the previous District Court ruling in Assoc. for Molecular Pathology et al. v. U.S. Patent and Trademark Office, 94 U.S.P.Q. 2d 1683 (S.D.N.Y. 2010). See also Alan J. Morrison's penetrating critique of Judge Sweet's ruling in: Rethinking the Gene Patent, 29 Biotech. L. Rep. 6, at 609-614 (2010).

[33] For a more detailed discussion cf. Timo Minssen, Es bleibet dabei: Eine schwedische Stellungnahme zur europäischen Debatte über den absoluten Erzeugnisschutz bei der DNA Patentierung, KLIFOR 3 at 93-97 & KLIFOR

4 at 105-120 (2008, in German), available at: www.lu.se/o.o.i.s?id=12588&postid=1145006 and (last visit 11 May 2011).

[34] Cf. Robert Fitt & Edward Nodder, An Uncertain Future for Gene Patents: The View from Europe, 29 Biotech. L. Rev. (6), at 615, 619-621 (December 2010) (Analyzing Case C-428/08, Monsanto Technology LLC, v. Cefetra BV of 6 July 2010.) Note further that on 9 December 2010 the EPO Enlarged Board of Appeal decided on the exclusion from patentability of "essentially biological processes" in the consolidated cases G 2/07-Broccoli/PLANT BIOSCIENCE and G 1/08-Tomatoes/STATE OF ISRAEL (concluding inter alia that "A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC").

[35] The facts of the case did not concern human DNA and the decision focused mainly on article 9 of the Biotech Directive. Yet, the decision also contains general statements on TRIPS and further stipulations of the Directive, such as Article 5. For further analysis and criticism of the judgment, cf. Michael A. Kock, Court of Justice of the European Union Limits Patents on DNA Sequences: Much Ado About Nothing or The Beginning of Erosion for Biotech Patents?, 11 BSLR 1, 3-12; Michael A. Kock. Purpose-Bound Protection for DNA Sequences: In Through The Back Door?; 5 JIPLP, 495-513 (2010).

[36] Referring to Christopher M. Holman, The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Legislation, 76 UMKC Law Rev. 295, 307 (2007). Cf. Kilger, Feldges, Jaenichen, The Erosion of Compound Protection in Germany: Implementation of the EU Directive on the Legal Protection of Biotechnology Inventions–The German Way JPTOS 7, 569 (2005).

[37] See e.g. Tine Sommer, The Scope of Gene Patent Protection and the TRIPS Agreement–An Exclusively Nondiscriminatory Approach?, 38 IIC 30 (2007).

[38] Cf. e.g. Joseph Straus, An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patents for Genes–An Academic Point of View, [2003] OJ EPO Special Issue 166; Cf. Product patents on human DNA sequences: where do we stand in Europe?, 326 Comptes Rendus Biologies 10, 1111-1114.

[39] The author refers to several empirical studies demonstrating that the existence of patents on genes so far had only an insignificant negative impact on biomedical research "as researchers in the biomedical have found working solutions."

[40] This has also been repeatedly emphasized by Joseph Straus, see e.g. Straus, in: Kieff (ed.), PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, Vol. 50 of Advances in Genetics (Elsevier Academic Press, 2003), 75. Cf. Minssen, supra n. 33.

[41] As noted by the editors in the preface.

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