

Experimental Use Exceptions and Australian Patent Act:

Submission to Advisory Council on Intellectual Property

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Abstract:

The experimental use exemptions have been an integral part of the patenting system around the world but it has taken different scale and scope depending upon countries and there is no uniformity in the practice followed around the world. There is no uniformity among the Members of the WTO regarding experimental use exemptions and every country has its distinctive provisions and judicial interpretations depending upon the government policy and some times because of the influence of the patent stake holders. While countries such as the USA have provided selective experimental use exceptions, countries like Japan have more flexible experimental use exceptions in their patent acts. The flexibility has permitted such countries to permit exploitation of patent as an instrument of advancement of science and technology against the concept of absolutism in monopoly propagated by the firms which have developed a deep stake in perpetuating the monopoly. The extension of patenting to the basic science, the research tools, softwares and even to pieces of DNA without bothering to determine its commercial utility has deleterious effect on the advancement of science particularly in the countries which have recently decided to concentrate on the development of science and technology such as Australia. Another aspect normally propagated is that the restrictiveness of patenting monopoly can be avoided through industry-institution partnerships but the conflict in the commercial aims and the scientific pursuit has invariably led to derailing of the scientific progress in such partnerships. However, the lack of clear cut exceptions normally leads to uncertainty and the uncertainty doesn't normally help in promotion of scientific progress and as noted by the Royal Society, prudent people normally avoid getting into conflict. Australia should provide clear cut rules and regulations to permit experimental use exceptions in its patent act so that the patenting monopoly should not stifle innovations instead of development of science and growth in innovations, the basis for the government authorized monopoly

A very important aspect of intellectual property rights has been the limitation on such rights of making, using, importing through a number of ways ranging from the common law doctrine of non-injury or damage by a violation of the incorporated rights¹ to specific exemptions provided

¹ Justice Curtiss codified this argument in *Byam v. Bullford* (1 Curt. 100, 4F Cas. 934 (C.C.D. Mass. 1852 NO. 2262)) when he observed

Nor can I find any solid foundation on which to rest the right of a patentee to support an action on the case for the violation of his exclusive right, except that settled and reasonable common-law basis of all such actions, injury and damage; injury by a violation of the incorporeal right, and damage, at least nominal, presumed by the law to arise from such violation. Such I understand to have been the principle proceeded upon by Mr. Justice Story, *Whittemore v. Cutter* [Case No. 17,600], where he held that making a machine for a philosophical experiment, or to test the sufficiency of the specification, would not be an infringement; and in *Sawin v. Guild* [Id. 12, 391], where he says the act must be with intent to deprive the patentees of some lawful profit; and also by Mr. Justice Patteson, in *Jones v. Pearce*, *Webst. Pat. Cas.* 125, where he excepts the making of a patented article for mere amusement, and not for profit. In these cases inasmuch as there was supposed to be no damage, there was thought to be no action. And though I am rather disposed ,

in the law on par with the fair use doctrine.² The experimental use exception from patenting rights is one of such limitation on patenting rights. The use of patent for experimental use purposes was mostly confined to the dispute between pharmaceutical companies where generic manufacturers were using the patented product to generate data to submit to regulatory authorities for approval till the US specialized court dealing with patent cases, the Court of Appeals for Federal Circuit (CAFC) in *Duke University v. Mady*³ decided that the educational institutions are indulging in the business of education and as such are indulging in violation of patent rights when they use patents for experimental purposes.⁴

The experimental use exception has a number of implications. One is the progress of basic research and the use of patent to test the validity of the patent and look for improvement. The other implication is the experimental use of patent before the expiry of the patent to generate data to get regulatory approval or to use the patented product itself to get the approval. The third implication is the use of the patent by the educational and non-commercial institutions to add to the progress of science and innovation. Linked to the third aspect is the question of transfer of such innovations for commercial purposes and the commercial collaboration with external firms. The experimental exemption to patenting monopoly as practiced in different countries has two aspects. One which is based on promotion of further development of the patent⁵ and the other where the exemptions have been specifically granted for collecting data to be submitted to the

with Mr. Justice Washington, in *Watson v. Bladen* [Case No. 17, 277], to doubt whether the assumption is correct, that in such cases there is no damage; yet if the assumption be correct, I think the inference is sound that no action lies.

² Judge Newman in her dissenting opinion in *Integra Life sciences v. Merck*, 331 F. 3d 860 (Fed. Cir. 2003) observed in note 9 “The research exemption has been compared to “fair use,” which was also a creation of Justice Story, in *Folston v. Marsh*, 98 Fed. Cas. 342, F. Cas. No. 4901 (C.C.D. Mass. 1841) (No. 4901). The House Report drew this analogy in discussing 35 U.S.C. 271(e)(1), stating: “Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.” H.R. Rep. No. 98-857 at 30 (1984), reprinted in 1984 USCCAN 2714”

³ *Madey v. duke University*, 307 F. 3d 1351 (Fed. Cir. 2002)

⁴ *Id.* at p. 1362, (“Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, , often sanction and fund research projects with arguably no commercial applications whatsoever. However, these projects unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also, serve, for example, to increase the status of the institutions and lure lucrative research grants, students and faculty. In short, regardless of whiter a particular institutions or entity is engaged in an endeavor for commercial gain, so long as the commercial act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.”

⁵ William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC 735 (1998).

regulatory authorities for approval purposes. In countries like the USA,⁶ Canada⁷ and New Zealand,⁸ Israel,⁹ South Africa,¹⁰ Argentina¹¹ etc., the later exception has been specifically provided for where as in Germany¹² and Japan,¹³ such data generation has been treated as coming within the compass of the exemptions under general experimental exemptions. There is another aspect where implication is where even the educational institutions have been prohibited from any use of the patent for experimental purposes on the specific plea that such institutions are in the business of education as in *Madey*.¹⁴ The elimination of experimental use exceptions in the USA has wider connotations because it became a basis for not only subsequent decisions in

⁶ 35 U.S.C. §§ 271(e)(1). Also referred to as Bolar Exemption

⁷ Canada Patent Act Section 55(2)(1)

⁸ With effect from 19 December 2002, the New Zealand Parliament has passed a significant amendment to the Patents Act. The new provision (section 68B) provides that:

"It is not an infringement of a patent for a person to make, use, exercise or vend the invention concerned solely for uses reasonably related to the development and submission of information required under New Zealand law or the law of any other country that regulates the manufacture, construction, use, or sale of any product".

The effect of the provision that it is no longer an infringement for a party to apply for regulatory approval for, say, a generic equivalent pharmaceutical or animal remedy prior to the expiry in New Zealand of patents governing the original product. Similarly it will not be an infringement to manufacture samples and conduct testing if required to meet regulatory requirements for registration either in New Zealand or under the law of any other country.

The New Zealand provision was taken from section 55.2(1) of the Canadian Patents Act. The Canadian provision was the subject of challenge before the WTO by the EU. In a lengthy decision issued on 17 March 2000, a WTO Panel upheld the Canadian provision, ruling that it was not inconsistent with Articles 27.1, 28.1, and 30 of the TRIPs Agreement. Canada Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS/114/R dated 17th March 2000 [hereinafter Canada Patent Protection]

⁹ Canada Patent Protection at 208. The Israeli provision says

Section 54A of the Law refers to experimental acts which are defined : "An experimental act, which is part of an effort to obtain license to market the product after the patent has lapsed, does not constitute "exploitation of an invention", if the following two conditions are met:

- (1) the effort to obtain a license is made in order to obtain a license in Israel or in a country, in which and experimental act on a patent protected invention for the purpose of obtaining a licence is permitted before the patent lapses;
- (2) any product produced under the terms of this Section is not used – both while the patent is in effect or thereafter – for any purpose other than obtaining a licence as aforesaid."

¹⁰ Richard Binns and Bryan Driscoll, Are the generic companies the battle? 89 *Managing Intell. Prop.* 36 (May 1999)

¹¹ Canada Protection at 30. Argentina Law 24.766 of December 1996, Article 8: "When a product or process is protected by a patent, any third party shall be able to use the invention before the expiration of the patent, with experimental aims and to gather the information required to use the invention before the expiration of the patent , with experimental aims and to gather the information required for the approval of a product or process by the competent authority, for its commercialization after the expiration of the patent."

¹² *Klinsche I and Klinishe II*, infra note 100 and 101

¹³ *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd*, Case No. 1998 (ju) 153 delivered on 16 April, 1999

¹⁴ *Madey v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002)

the USA through Roche Products, the judges from other countries have also used the decision in *Roche Products* to narrow down the exemption.¹⁵

The modern patenting monopoly although has its origin in 1624 Statute of Monopolies¹⁶ it had taken different paths depending upon a country's social, economic and political environment and institutions including judiciary. In the USA, the patenting monopoly originated from the US Constitution Article 8.1 which empowered Congress to permit limited monopoly if that monopoly helps in progress of Arts and science.¹⁷ Similar public purpose has been the backbone of patenting monopoly in Germany and Japan, two of the major developed and scientifically advanced countries.¹⁸

In Australian Patent Act, there is no clear cut exemption for the experimental use even as a de minimis clause and there is no corresponding example on par with Section 271(e) in the USA or Section 55(2)(1) in Canada for submission of requisite data to third parties although through an amendment in 1998, the Australian Patent Act permits the use of patent to generate data for approval to regulatory authorities during the extension of patent.¹⁹ Previous to this there were provisions (Sections 70-75) under the Australian Patent Act 1990 for a four year extension of

¹⁵ *Smith Kline and French Laboratories Ltd. V. Douglas Pharmaceuticals*, [1991] FSR 522, 11 BMLR 126 (NZ Ct. of Appeal, 1991). Judge Cooke was quite forthcoming in observing that "Perhaps it as well to add that in relation to patent laws one should be wary, in my opinion, of indigenous common law developments unless they are clearly required: see *Wellcome Foundation Ltd. V Commissioner of Patents* [1983] NZLR 385. The New Zealand courts are operating in an international environment where consistency of approach is important."

¹⁶ In 1610, James I was forced by mounting judicial criticism and public outcry to revoke all previous patents and declare in his "Book of Bounty" that 'monopolies are things contrary to our laws' and "we expressly command that no suitor presume to move us". He stated an exception to this ban for "projects of new invention so they be not contrary to the law, nor mischievous to the State". The concept of public policy is the backbone of the modern patenting monopoly. The Statute of Monopolies of 1624. Section 6 of the Statute rendered illegal all monopolies except those "for the term of 14 years or under hereafter to be made of the sole working or making of any manner of new manufactures within this Realm to the true and first inventor"; such monopolies should not be "contrary to the law nor mischievous to the State by raising prices of commodities at home or hurt of trade". 21 Jac. I, ch. 3 (1624) (Eng.)

¹⁷ The US Constitution authorizes US Congress to enact laws to "promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive rights to their writings and discoveries." U. S. constitution. Art. 1, S. 8, cl. 8.

¹⁸ A Study by the U. S. Department of Commerce and CHI Research, Inc. has shown that Japan and Germany are next to the USA in terms of patenting. Michael B. Albert, Phyllis Genther Yoshida and Debra van Opstal *The New Innovations: Global Patenting Trends in five Sectors*, U. S. Department of Commerce, Office of Technology Policy, September 1998

¹⁹ The Intellectual Property Law Amendment Act 1998 amended the Australian Patent Act 1990 to introduce a patent term extension scheme for pharmaceutical patents along with a limited exemption for experimental use for those pharmaceutical products which have been awarded extension of patent terms.

the term of patents relating to pharmaceutical substances where the patentee had applied for marketing approval but after the second year of extension, the generic manufacturers were granted exemption from infringement for the purpose of obtaining marketing approval. (Section 76). The extraordinarily strict patenting regime in Australia does not appear to have helped in the Australian scientific growth and new technological innovations.

The position of science and technology as reflected in the report prepared by CHI Research Inc. on behalf of the Australian Research Council (ARC) and the Commonwealth Scientific and Industrial Research Organisation (CSIRO),²⁰ does not appear to be very bright. It was found that 90 percent of the of the scientific research papers cited in Australian-invented U.S. Patents issued to private companies are authored at publicly funded organizations-either in Australia or elsewhere and when it came to Australian scientific research papers cited in all Australian-invented U.S. Patents, 97 % of citations are to Australian papers or authored at publicly funded institutions.²¹ However, the number of patents in the USA having Australian inventor is only on par with those of Finland and the Australian invented patenting in the U.S. patent system in 1997 is just 0.5 percent and has shown practically no growth (0.47 percent in 1979).²² The extraordinarily strict patenting regime has not generated a significant growth in the development of Australian science and technology.²³ The Australian patenting is normally confined to mechanical and manufacturing technologies and very few in electronics.

The report underlined two areas as that of major concern. These are

1. the dominance of older, less science-linked areas of technology, and
2. a degree of lack of visibility of Australian science to the rest of the world.²⁴

A very important aspect of the experimental use exemption is that there is no uniform practice of exemption even among Members of the OECD. Even the Members of the EC who have supposedly incorporated Article 27 of the European Patent Convention have different

²⁰ F. Narin, M. Albert , P. Koll and D. Hicks, *Inventing Our Future: The Link Between Australian Patenting and Basic Science*, A Report prepared by CHI Research for ARC and CSIRO, Australia (2000)

²¹ *Id.*

²² *Id.* at p. 12

²³ *Id.* at 12. CHI used 'current impact index' – how often the most recent five years of Australian patents are cited in world patents in the current years suggesting that Australian patents are not high impact on world patents as Australian is virtually at the bottom of the chart.

²⁴ *Id.* at 17

interpretations of this Article.²⁵ While the experimental use exemption has been virtually removed from the USA except those specifically provided for as in Section 271(1)(e), a number of countries have provided for general exemption along with the specific exemption pertaining to regulatory approval.

The scale and scope of the experimental use exception also depend upon the influence of industries, whose profitability depends upon patenting monopolies, on the political institutions concerned. Sometimes such influence extends to other institutions such as the judiciary as in the case of the Court of Appeals for Federal Circuit which was originally constituted to bring uniformity in the interpretations of patenting provisions in the USA.²⁶ However, the Court of Appeals over a number of years has transformed itself into a promoter of monopoly of the patent holders.²⁷ This transformation was also influenced by the appointment of judges either having patenting bias or because of their close association with the industries. For example, judge Rich was appointed as a judge although he was deeply involved with the drafting of the US Patent Act 1952. Judge Lourie was chairman of IFAC-3, an industrial group- which is supposed to advise the Commerce Secretary but is essentially an industry lobby group. Judge Newman was in the Committee which recommended the establishment of Court of Appeals. The decision of this institution went against the decisions of a number of the US Supreme Court's decisions.²⁸ At times, it was perceived by some scholars as if the Court of Appeals has not only

²⁵ William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC 735 (1998).

²⁶ Pub. L. No. 97-164, Stat. 25 (1982); S. Rep. No. 97-275, at 2 (1981)

The Federal Court Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982), created the Court of Appeals for the Federal Circuit gave it exclusive jurisdiction over all appeals of patent cases originally heard in the federal district courts. Burchfiel, s. 1.2 at 5. In its first decision, the Federal Circuit held prior rulings of the Court of Claims and of the Court of Customs and Patent Appeals to be binding precedent. (*South Corp. v. United States* 690 F. 2d 1368, 1370 (Fed. Cir. 1982) en banc)

²⁷ Robert Desmond, *Nothing Seems Obvious to the Court of Appeals for the federal Circuit: The Federal Circuit, Unchecked by the Supreme court, Transforms the Standard of Obviousness Under the patent Law*, 26 Loy .L. A. L. Rev. 455 (1993); Victoria Slind-Flor, *Federal Circuit Judged Flawed*, National Law Journal , Aug. 3, 1998; *Holms Group Inc. v. Vornado Air Circulation System Inc.*, 535 U.S. 826, 838-39 (2002) Justice Stevens stated that "occasional [patent] decisions by [regional] circuits] courts [are needed to] provide an antidote to the risk that the Federal Circuit may develop institutional bias."

²⁸ Debra D. Petersen, *Can this Brokered Marriage breaking Relationship Between the Supreme Court and the Federal Circuit in Patent Law Jurisprudence*, 2 J. Marshall Rev. of Intellect. Prop. L. 201, 211 (Within the first two years of the Federal Circuit's existence, Markey authored opinions "expressly repudiating most of the troublesome patent rulings of the Supreme Court." Markey's action dripped with testosterone: here was the Chief Judge of a brand new intermediate appellate court, whose decisions were subject to review by the Supreme Court, explicitly rejecting the law as defined by the Supreme Court.")

replaced the US Supreme Court but has specifically been created to eliminate decisions of the US Supreme Court.²⁹ The precedents were either reconstituted or ignored³⁰ or sometimes entirely opposite meanings were attributed.³¹ Similar nonjudicial developments took place in the EC when the institution of Advocate General was inserted between the parties and the judges of the European Court of Justice (ECJ). The Advocate General's opinions essentially have political implications but are treated by the ECJ as judicially persuasive. Such pronouncements of the ECJ become binding on the Members of the EC.³²

Although Australia has a historical linkage with the UK judicial institution but in view of the formation of the European Court of Justice and introduction of a non-judicial institution such as that of the Advocate General of the ECJ, such linkage with the UK judicial institutions is no longer as strong as it used to be. In such situation, Australia has to adopt its own independent decision in conformity with the international treaty obligations Australia has decided to be party to regarding the extent and scope of patenting monopoly.

The experimental use exception also has direct link with the University-Industry partnership and it is important that any discussion of the experimental use exemption should also explore the issue of transfer of technology.

In the light of above introduction, I will first discuss the points raised in the Issue Paper³³ followed by my suggestions regarding scale and scope of the experimental use exemption. I will also discuss the implication of public-private partnership and that of transfer of technology in

²⁹ Andrea D. Brashear, *Evolving Biotechnology Patent Laws in the United States and Europe: Are they inhibiting Disease Research?* *Indiana International & Comparative Law Review*, 2001, pp. 183-218

³⁰ *Roche Products, Inc. v. Bolar Pharmaceutical s Co.* 572. F. Supp. 255, p. 258, subsequently reversed by Court of Appeals in *Roche Products, Inc. v. Bolar Pharmaceuticals Co.* 733 F. 2d 858 which in turn was overruled by Bolar Exemption by introduction of Section 271(e) in the US Patent Act; The Federal Circuit reconstituted the Pitcairn decision . (discussed later).

³¹ *Anton/Bauer v. PAG Ltd*³¹ where the Federal Circuit confirmed the decision of the District Court -Anton Bauer v. PAG, 2002 U.S. Dist. LEXIS 11583 (D. Conn. June 13, 2002). It said "The Supreme Court enunciated this doctrine when it stated that "incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, and upon familiar principles the authorized sale of article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold." *United States v. Univis Lens Co.* (316 U.S. 241, 250-51, 53 U.S.P.Q. (BNA) 404, 408, 86 L. Ed. 1408, 62 S. Ct. 1088 (1942)) In other words, sale of an unpatented article exhausts the seller's right to control the future sale and use of that article, but only in certain circumstances exhausts the seller's patent rights and result in an implied license." The US Supreme Court in *Univis* did not distinguish between patented or unpatented goods.

³² *Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission* Case C-377/98) Court of Justice of the European Communities [2002] All ER (EC) 97

³³ Advisory Council on the Intellectual Property, Patents and Experimental Use, Issue Paper, February 2004

such partnership. Because of the significant implications of the decision in *Roche Products*, it would be discussed to explain its legality.

Experimental Use Exception in the USA

The experimental use exemption in the USA has a long history and did not end up with Poppehausen as claimed by the Federal Circuit in *Roche Products v. Bolar*.³⁴ The experimental use exception is based on common law doctrine in the USA and Canada. The first significant exposition of the experimental use exception in the US comes from the US Supreme Court Justice Story's opinion in *Whittemore v. Cutter* where he observed

"It could never have been the intent of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for purpose of ascertaining the sufficiency of the machine to produce its described effects."³⁵

In the subsequent decision in *Sawin v. Guild*,³⁶ Justice Story clarified his opinion in *Whittemore* and observed that "... the making of patented machine to be an offence within the purview of it, must be the making with intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. *Whittemore v. Cutter* [Case No. 17,600]. In other words, that the making must be with intent to infringe the patent right, and deprive the owner of the lawful rewards of his discovery."³⁷

The main emphasis of the patent right was on the harm caused to the patent holder during the term of the patent. This norm continued till in 1984, the Court of Appeals formed to exclusively deal with the patent issues ignored Justice Story's interpretation in *Sawin v. Guild* of *Whittemore* and the emphasis of Judge Story on harm to the commercial interest of the patent holder and decided to read *Whittemore v. Cutter* as permitting experimental use exceptions merely for curiosity and philosophical purposes as contemporaneously understood.

The term philosophical purpose has recently become an issue of contention when Judge Newman in her opinion in *Integra Life Sciences*³⁸ discussed its meaning in 1813 when the term philosophy was synonymous with science. This argument was subsequently expanded by Wegner who went through old dictionaries and literature to confirm that Justice Story's philosophical purposes was

³⁴ *Roche Products v. Bolar Pharmaceuticals* 733 F. 2D 858 (Fed. Cir. 1984)

³⁵ *Whittemore v. Cutter*, 1 Gall. 429, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813)(No. 17,600)

³⁶ *Sawin v. Guild*, at p. 555

³⁷ *Sawin v. Guild*, at p. 555

³⁸ *Integra Life Sciences v. Merck*, 331 F.3d 860, 875 (Fed. Cir. 2003)

essentially directed to scientific experiments.³⁹ However, Justice Story's interpretation in *Sawin v. Guild* was directed to the commercial harm done to the patent holder and not restricting the exemption in the US Patent Act to mere scientific experiments.

The decision of the Federal Circuit in *Roche Products v. Bolar Pharmaceuticals*⁴⁰ where the court reconstructed the judgment of the Court of Claims in *Pitcairn*⁴¹ to remove experimental use totally by limiting it to satisfaction of curiosity and philosophical purpose as contemporarily understood.

The Court of Claims in *Pitcairn* had observed

The plaintiff has excluded from its present claim static test mechanisms manufactured for the defendant. Numerous research and development contracts were entered into by the defendant and various manufacturers for the design, development and manufacture of experimental helicopters and none of those specific helicopters are the subject of this litigation. Defendant urges the court to exclude from compensation any aircraft used by the defendant for testing, evolutional, demonstrational or experimental purposes. Use for such purposes is use by or for the Government and is compensable. Obviously every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors. Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation. (*Pitcairn v. United States*, 212 Ct. Cl. 168, p. 200)

The above observation of the *Pitcairn* court excluded experimental use helicopters used for numerous researches and developments from patenting provisions. The *Pitcairn* court did not extend such exemption to the helicopters which were tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range i.e. it did not exclude particular type of tests by specifically mentioning "experiments of such nature."

³⁹ Harold C. Wegner, The Post Madey Research Exemption, available at <http://www.foley.com/people/bio.aspx?employeeid=16338&&practiceID=&industryID=&genPageID=>

⁴⁰ 733 F. 2D 858(Fed. Cir. 1984)

⁴¹ *Pitcairn v. US*, 212 Ct. C. 168 (1976)

The Court of Appeal for the Federal Circuit in *Roche Products* reconstituted the observation of the Pitcairn court and removed the term “such nature” referring to particular type of tests. It observed

Pitcairn, the most persuasive of the Court of Claims cases concerning the experimental use defense, sets forth the law which must control the disposition of this case: “tests, demonstrations, and experiments *** which are in keeping with the legitimate business of the *** alleged infringer” are infringements for which “experimental use is not a defense.”

This essentially amounts to doctoring a paragraph to give an entirely new meaning by making a sentence applicable in general when it was specifically made for a very limited situation. What the Court in *Pitcairn* had observed that the tests meant for testing of helicopters for stability and vibrations etc would not qualify as the experimental use. The word used was “such nature” which was removed by the Federal Circuit from its quote to suggest that any test, demonstration and experiments would not qualify for experimental exemption. *Pitcairn* specifically excluded a number of helicopters and other instruments manufactured for experimental purposes. What *Pitcairn* did not exclude from use under the experimental use exceptions from the patenting infringement were helicopters used for testing “the lifting ability, for the effect of vibration on installed equipment, flight speed and range and engine efficiency.” The Court of Claims was critical of its previous decision in *Chesterfield*⁴² but it did not overrule *Chesterfield* nor limited the experiential use exemptions to satisfy the philosophical curiosity. The judgment in *Roche Products* was an example of judicial lawlessness described by Farnsworth⁴³ where not only relevant judicial pronouncements were ignored although they were present before the judges, the precedential judicial pronouncements were reconstructed to come to a new and possibly a predetermined conclusion.

The Federal Circuit’s decision in *Roche Products v. Bolar Pharmaceuticals* was picked up by the New Zealand Court of Appeals⁴⁴ to narrow down the experimental use exemption in New Zealand. Unfortunately, the recent developments suggest that decisions of the US Courts in these areas are becoming binding precedents for courts in other countries such as the EC and Canada.

⁴² *Chesterfield v. United States*, 141 Ct. Cl. 838, 840, 159 F. Supp. 371 (Ct. Cl. 1958)

⁴³ Farnsworth, W. 2001: “‘To Do a Great Right, Do a Little Wrong’: A User’s Guide to Judicial Lawlessness”, Working Paper Series, Public Law and Legal Theory Working Paper No. 01-18, School of Law, Boston University)

⁴⁴ *SmithKline and French Laboratories v. Douglas Pharmaceuticals* [1991] FSR 522

In Canada, the dissenting judges in *Commissioner of Patents v. President and Fellows of Harvard College*,⁴⁵ were virtually relying on the US Supreme Court's doctrine of "anything under the sun that is made by man" propounded in *Diamond v. Chakrabarty*⁴⁶ and *Diamond v. Diehr*⁴⁷ to push for patenting of Harvard Mouse better known as DuPont Mouse because DuPont had exclusive license for this patent from the Harvard University. Similarly, in *Netherlands (supported by Italy and another) v European Parliament*,⁴⁸ the Advocate General in the EC depended upon *Diamond v. Chakrabarty* to push for acceptance of the EC Biotechnological Directive⁴⁹ by other Members of the European Union.

Roche Products and Bolar Exemption

The right of excluding third parties from 'making' or 'use' of patented product in an exceptionally restrictive manner was arrived at by the US Court of Appeals for the Federal Circuit which many consider was specifically established to extend the patenting monopoly in the name of bringing uniformity and harmonization in the interpretation of patent act.. Subsequently it conceded that in view of a number of judgments,⁵⁰ the exclusion of the third parties from using the patented product cannot be taken to its utmost possible scope.⁵¹

The Court of Appeals appear to be mocking decision of the Supreme Court Justice Story in *Whittemore* when it observed

The so called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while

⁴⁵ *Commissioner of Patents v. President and Fellows of Harvard College*, 2002 SCC 76

⁴⁶ *Diamond v. Chakrabarty* 447 U.S. 330 (1980)

⁴⁷ *Diamond v. Diehr* 450 U.S. 175 (1981)

⁴⁸ *Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)* Case C-377/98) Court of Justice of the European Communities [2002] All ER (EC) 97

⁴⁹ EC Biotechnological Directive

⁵⁰ *Pittcairn v. United States*, 212 Ct. Cl. 168, 547 F.2d 1106, 192 U.S.P.Q. (BNA) 612 (1976), cert. Denied, 434 U.S. 1051, 54 L. Ed. 2d 804, 98 S. Ct. 903 (1978) (experimental use may be a defense to infringement); *United States v. Univis Lens Co.*, 316 U.S. 241, 86 L. Ed. 1408, 62 S. Ct. 1088 (1942) ("An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, .. "Id. At 249); *General Electric Co.*, 316 United States, 215 Ct. Cl. 636, 572 F.2D 745, 198 U.S.P.Q. (BNA) 65 (1978) ("It can be properly assumed that as part of the bargain the seller of a device incorporating a patented combination properly authorizes the buyer to continue to use the device so long as the latter can and does use the elements he purchased from the patentee or licensor." Id. At 784-85, 198 U.S.P.Q. (BNA) at 98

⁵¹ *Roche Products*, p. 861

on circuit in Massachusetts. In *Whittemore v. Cutter*, 1 Gall. 429, 29 F. Cas. 1120, 1121 (C.C.D. Massachusetts. 1813) (No. 17,600), Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use a patented invention for profit, stating:

'It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for purpose of ascertaining the sufficiency of the machine to produce its described effects.'

Despite skepticism, see e.g. *Byam v. Bullard*, 1 Curt. 100, 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262) (opinion by Justice Curtis), Justice Story's seminal statement evolved until, by 1861, the law was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for amusement is not an infringement of the rights of the patentee." *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).⁵²

The CAFC, while discussing *Whittemore* did not mention the interpretation of *Whittemore v. Cutter*, in *Sawin v. Guild*⁵³ where Justice Story of the US Supreme Court himself interpreted his own judgment in *Whittemore* although Justice Curtiss in *Byam* had specifically referred to *Sawin v. Guild* while elaborating the common law doctrine.⁵⁴

⁵² *Roche Products, Inc. v. Bolar Pharmaceutical Co.* 733 F.2d 858 p. 862

⁵³ *Sawin v. Guild*, p. 555

⁵⁴ The skepticism of Justice Curtis in *Byam v. Bullard*, 1 Curt. 100, 4F Cas. 934 (C.C.D. Mass. 1852 No. 2262) is:

Nor can I find any solid foundation on which to rest the right of a patentee to support an action on the case for the violation of his exclusive right, except that settled and reasonable common-law basis of all such actions, injury and damage; injury by a violation of the incorporeal right, and damage, at least nominal, presumed by the law to arise from such violation. Such I understand to have been the principle proceeded upon by Mr. Justice Story, *Whittemore v. Cutter* [Case No. 17,600], where he held that making a machine for a philosophical experiment, or to test the sufficiency of the specification, would not be an infringement; and in *Sawin v. Guild* [Id. 12, 391], where he says the act must be with intent to deprive the patentees of some lawful profit; and also by Mr. Justice Patteson, in *Jones v. Pearce*, Webst. Pat. Cas. 125, where he excepts the making of a patented article for mere amusement, and not for profit. In these cases inasmuch as there was supposed to be no damage, there was thought to be no action. And though I am rather disposed, with Mr. Justice Washington, in *Watson v. Bladen* [Case No. 17, 277], to doubt whether the assumption is correct, that in such cases there is no damage; yet if the assumption be correct, I think the inference is sound that no action lies.⁵⁴

The CAFC also made a wrong claim that the law pertaining to experimental use was well settled by 1861 in Poppenhusen. In *Bonsack Machine Co. v. Underwood*,⁵⁵ the experimental use was discussed in 1896, much after *Poppenhusen* where experimental use exemptions were confirmed on the basis of Justice Story's observations in *Sawin v. Guild*. Based on *Sawin v. Guild*, the Court in *Steam Stone Cutter v. Sheldons* observed that "The mere sale of the materials of a machine, complete and fit for operation, would not be an infringement of the patent on machine, unless the sale was for use."⁵⁶ The above decisions laying down the law in the USA make it apparent that simple making does not constitute an infringement unless it means making for profit at the expense of the patent holder in the territory of the patent.

The experimental use was also discussed in a number of Court of Claims decisions. There was a consistent approach till *Pitcairn*⁵⁷ (where the Claims Court did not overrule the previous decisions of the Court of Claims in *Chesterfield*⁵⁸ but tried to distinguish them from the facts of *Pitcairn* by suggesting that "In present case there is no evidence in defendant's offer of proof that any of the helicopters to which defendant's "experimental use" contentions pertain were build solely for experimental purposes."

In *Chesterfield v. United States*, 141 Ct. Cl. 838, 159 F. Supp. 371 (Ct. Cl. 1958), the Claims Court observed "Moreover, if these two claims are construed to be valid over the prior art and to be definite, the claims are not infringed by the accused S-816 alloy; the claims are not infringed by the use of the accused 422-19 alloy, and the claims are not infringed by the use, if any, of all 6059 alloys."⁵⁹

This observation, the Court of Claims in *Cheserfield* made after its observation in para 44 made it clear that the decision of the Court of Claims was not an *obiter dictum* but a well thought out proper judicial decision. The Court of Claims in para 44 said

If there was any skepticism on the part of Justice Curtis, he did not let that stop him from confirming *Sawin v. Guild*.

⁵⁵ 73 F. 206, 211 (E.D.N.C. 1896)

⁵⁶ 21. F. 875, 876 (D.V. 1884)

⁵⁷ *Pitcairn v. United States*, 212 Ct. Cl. 168)

⁵⁸ *Chesterfield v. United States*, 141 Ct. Cl. 838, 159 F. Supp. 371 (Ct. Cl. 1958)

⁵⁹ *Chesterfield v. United States*, 141 Ct. Cl. 838, 159 F. Supp. 371 (Ct. Cl. 1958), pp. 865-866

The defendant has admitted that it procured, within the accounting periods set forth in finding, a total of 3,679 pounds of an alloy designated as 422-19. The defendant has admitted that some of the foregoing 422-19 alloy was formed into 101 turbo-supercharger buckets delivered to an agency of the defendant for experimental use and testing. There is no evidence that defendant's use, if any, of the remainder of said 422-19 alloy was other than experimental.⁶⁰

In *Pitcairn*, the Claims Court did not and possibly could not overrule *Chesterfield* and tried to distinguish the observation in *Chesterfield* by noting

“The defendant's reliance on the Court's opinion in *Chesterfield*, supra, is likewise without merit. The Court's statement in its opinion there that experimental use does not infringe constituted pure obiter dictum. The Court's opinion specifically stated:

“Where the court finds as a fact that the patent claims in suit are clearly invalid *** it may not be necessary to consider the issue of infringement. 141 Ct. Cl. At 840.”⁶¹

The Court of Claims in *Pitcairn* further observed:

The court's reference to experimental use was clearly unnecessary to the disposition reached in *Chesterfield*. It is also noted that in *Chesterfield* the defendant procured by purchase, not by manufacture or for the Government, certain alloys, which had been developed and used for supercharger buckets, and blades. In *Chesterfield*, the claim arose from defendant's use of purchased alloys. In the present case, the infringing aircraft's were clearly manufactured for the defendant.⁶²

The *Chesterfield*'s opinion quoted by in *Pitcairn* is not appropriate as the concerned sentence did not deal with the decision at all. The sentence has been picked up from the paragraph of the Commissioner's opinion, which reads:

⁶⁰ *Chesterfield v. United States*, 141 Ct. Cl. 838, 159 F. Supp. 371 (Ct. Cl. 1958), p. 863

⁶¹ *Pitcairn v. United States*, 212 Ct. Cl. 168, p. 199

⁶² *Pitcairn v. United States*, 212 Ct. Cl. 168, p. 200

Two issues are before the court, first, the validity of the two claims in suit, and, second, whether the defendant has infringed said patent claims. It is recognized that, of those two issues, validity has the greater public importance. *Sinclair & Carroll Co. Inc. v. Interchemcial Corp.* 325 U.S. 327, 65 USPQ 297. Where the court finds that the patent claims in suit are clearly invalid for want of invention, it may not be necessary to consider the issue of infringement. *The Dow Chemical Company v. Halliburton Oil Well Cementing Company*, 324 U.S. 320, 64 USPQ 412⁶³

What has been quoted by the *Pitcairn* Court was not the opinion at all but just a general principle of interpretation in terms of Supreme Court judgments. The opinion is in paragraph 52, which says:

Summarizing, claims 5 of the '934 patent and claim 4 of the '935 patent are found to be invalid over the prior art and to be invalid for indefiniteness. Moreover, if these two claims are construed to be valid over the prior art and to be definite, the claims are not infringed by the accused S-816 alloy; the claims are not infringed by the use of the accused 422-19 alloy, and the claims are not infringed by the use, if any, of all 6059 alloys.

Conclusion of Law

Upon the foregoing findings of fact, which are made a part of the judgement herein, the court concludes as a matter of law that claim 5 of plaintiff's patent 1,698, 934 and claim 4 of plaintiff's patent 1,698,935 are both invalid. It is also found that the claims are not infringed by the defendant. Plaintiff is not entitled to recover and his petition is dismissed.⁶⁴

The decision in *Chesterfield* does not leave in doubt that the experimental use of the patented product having commercial implications does not amount to infringement nor *Pitcairn* court ever said that although it was quite harsh in its observation regarding experimental use exemption.

⁶³ *Chesterfield v. United States*, 141 Ct. Cl. 838, 840, 159 F. Supp. 371 (Ct. Cl. 1958)

⁶⁴ *Pitcairn*, Tests, Demonstration of such nature, ? p. 866

Similarly, the waiver of remuneration for using alloys for experimental use for supercharger buckets and blades was attempted to be distinguished by the Court of Claims in *Pitcairn* by distinguishing procurement by purchase, not by manufacture by or for the Government, and then used. *Pitcairn* does not suggest that experimental use exceptions are not permitted or are limited to philosophical purposes or that commercial nature of the experimental use of the experiment is prohibited.⁶⁵

It did not make it a rule or tried to overrule previous judgments of the higher courts as argued by the CAFC in its assertion by selectively quoting the above paragraph “tests, demonstrations, and experiments [which] are in keeping with the legitimate business of the [alleged infringer]” are infringement for which “experimental use is not a defense.” The emphasis on commercial nature i.e. concerning or affecting profit as the basis of all patenting rights have repeatedly been made in a large number of judicial decisions.

In spite of its tendentious use and non-use of preceding judgments, the Court of Appeals in *Roche Products* observed that: “We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of “scientific inquiry”, when that inquiry has definite, cognizable, and not insubstantial commercial purpose.”⁶⁶ The ultimate observation of the CAFC is based on the substantial “commercial” purpose behind the use of a patented product.

Roche Products was followed in two subsequent cases of *Deuterium*⁶⁷ and *Embrex*.⁶⁸ *Deuterium* was a decision by Judge Rader of the Court of Claims where the Court of Claims confirmed that an experimental use does not infringe.⁶⁹ However, it tried to follow *Pitcairn* and *Roche Products* to narrow down the experimental use to the so called philosophical purposes. The *Deuterium* decision is noticeable for two reasons. One is that it has quoted *Pitcairn* without removing the term “such nature”⁷⁰ and second that it has arrived at two distinct definitions of the term “experimental use”, one when it is used in Section 102(b) of Title 35 and another when it is used

⁶⁵ *Pitcairn*, pp. 199-200

⁶⁶ *Roche Products*, p. 863

⁶⁷ *Deuterium Corp. v. the United States*, 19 Ct. Cl. 624 (1990)

⁶⁸ *Embrex v. Service Engineering Corp.* 216 F. 3d 1343 (Fed. Cir. 2000)

⁶⁹ *Deuterium*, supra note ---, p. 631. This conclusion was based on the decision of *Chesterfield v. United States*, 141 Ct. Cl. 838, 846, 159 F. Supp. 371 (1958) and *Finney v. United States*, 202 Ct. Cl. 1130 (1973)

⁷⁰ *Deuterium*, at p. 631. The reference of the quote is *Pitcairn*, 542 F. 2d at 1125-26

after an inventor secures a patent. Essentially, the Deuterium court has followed *Roche Products* to narrow down the experimental use exception. The Deuterium court's distinction of the term experimental use before and after the patent is difficult to categorize within judicial norms. The Deuterium court also removed the de minimis concept enunciated in *Douglas v. United States*⁷¹ in case of patenting monopoly.⁷² These exceptional decisions possibly led to elevation of Judge Rader from the Court of Claims to the Court of Appeals for Federal Circuit. The next decision was that of the Federal Circuit in *Embrex*.⁷³ Where Judge Rader again reiterated his view in *Deuterium* by insisting that "the Patent Act (US) leaves no room for any de minimis or experimental use excuses of infringement."⁷⁴ The Federal Circuit in *Madey* did not accept the irrelevance of intent as decided by the Supreme Court in *Warner Jenkinson*⁷⁵ as reading the total abolition of the experimental use defense mentioned by Judge Rader in his concurrent opinion but it read the legitimate business in *Pitcairn* as covering each and every institution whether for profit or non-profit.⁷⁶ The Madey Court observed

"Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including education and enlightening students and

⁷¹ *Douglas v. United States*, 181 USPQ170 (Ct. Cl. Trial division 1974), aff'd, 206 Ct. Cl. 96510 F. 2d364 (1975)

⁷² *Deuterium*, p. 631

⁷³ *Deuterium*, p. 632, ("This court, however, declines to apply these factors (Several objective factors enunciated by the Federal Circuit showing experimental use) because they evolved for a very different purposes. These factors provide protection for an inventor who has yet to secure a patent. The experimental use exception to a public use or sale protects an inventor's intellectual property for the period of development and testing prior to patent application. The experimental use exception to infringing uses on the other hand, narrows the scope of intellectual property protection. This separate experimental use exception protects an individual making unauthorized use of a patent (a potential infringer) during tests seeking advancement or commercialization of the patented teaching. Thus, the broader objective standards developed to protect an inventor during experimentation prior to patent application do not apply to experiments by a potential infringer.")

⁷⁴ *Embrex*, at 1352-53 ("Turning next to the experimental use excuse, neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity. Rather, the Supreme Court and this court have recently reiterated that intent is irrelevant to infringement. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 529 U.S. 17, 34, 137 L.Ed. 2d 146, 117 S. Ct. 1040 (1997) ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent. ...").

⁷⁵ *Warner Jenkinson v. Hilton Davis chem. co.*, 529 U.S. 17, 34, 137 L. Ed. 146, 117 S. Ct. 1040 (1997)

⁷⁶ *Madey* at 1362.

faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.”⁷⁷

Madey has to be read with the Solicitor General’s amici curiae to understand the interaction between the governmental policy and the judicial decisions. On 30th April 2003, the US Supreme Court asked the US solicitor General to file his brief expressing the views of the United States Government⁷⁸ and apparently after getting the opinion of the Solicitor General, the US Supreme Court decided not to issue certiorari.⁷⁹ The Solicitor General on being asked by the US Supreme Court to file its amici curiae insisted that the above observation of the Federal Circuit would not hurt the progress of science in the USA and has to be read in its totality. It insisted that

“While petitioner (Duke University) asserts that a more robust exception of experimental use is needed to accommodate university research in particular, the existing case law does not establish such an exception and any substantial altering of the balance between the goals of the patent laws and the demands of academic research calls for judgments that are legislative, not judicial, in nature. Petitioner argues that the federal Circuit’s decision will render the experimental use defense unavailable to research institutions simply because their “legitimate business” is research. Pet. App. 25a. Although some language in the opinion, in isolation, could support such as argument, that approach is not compelled by the decision when read as a whole.”⁸⁰

The Solicitor General further argued

“Petitioner (Duke University) (Pet. 13) argues that the Federal Circuit’s recitation of Pitcairn’s legitimate business” language will strip academic institutions of the experimental use defense altogether, explaining that “[n]o research institution will be able to demonstrate that its experimental use of any patent fails to further the institution’s ‘legitimate business,’” “[b]ecause such entities are ‘in the business’ of research and education.” (Pet 14). Although some language in the court of appeal’s decision (see Pet. App. 25a) could support such an interpretation, that interpretation of the decision would produce the anomalous and untenable result of subjecting research institutions to a disfavored status under the experimental use defense. Moreover, read as

⁷⁷ Id.

⁷⁸ *Duke University v. John Madey*, 123 S. Ct. 1777

⁷⁹ *Duke University v. John Madey*, 123 S. Ct. 2639

⁸⁰ *Duke University v. Madey*, Brief for United States as Amicus Curiae filed by the US solicitor General, No. 02-1007 available at <http://www.usdoj.gov/org/briefs/2002/2pet/6invit/2002-1007.pet.ami.inv.pdf>, p. 5

a whole, the court's decision is fairly susceptible of a much more routine and evenhanded application of the defense."⁸¹

Notwithstanding the assertion of the Solicitor General in the USA, the Court in *Applera Corporation*⁸² without much argument rejected the experimental use defense of a research institution on the basis of *Madey*. Quoting *Madey*, the District Court decided that "the defense does not immunize "any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications.""⁸³

In *Integra*, this question was discussed but the Merck, the defendant did not want to argue on this issue although Judge Newman was more than sympathetic on the issue of experimental use exceptions.⁸⁴ The concerned industries were quite keen to keep the experimental use exceptions to the minimum possible and the presence of Judge Rader in the bench took care of the rest.

The discussion suggests that the development leading to the US experimental use exception is unique to the USA and reflects a compliability of the judicial institution to the governmental policy which even if it leads to diminution of research and increase in the cost of research may not hurt the US technology in the short run but for countries like Australia which is in the initial threshold of technological progress, it had to formulate its own policy taking into consideration its present technological status and its economic progress along with the state and need of its educational institution.

⁸¹ Id. at 10

⁸² *Applera Corporation v. MJ Research Inc.* 2004 U.S. dist. LEXIS (D. Conn. 2004), pp. 5-9

⁸³ Id. at 7

⁸⁴ *Integra Life Sciences*, supra note – at 863 ("n. 2 IN her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in *Madey v. Duke*. However, the common law experimental use exception is not before this court in the instant case. The issue before the jury was whether the infringing pre-clinical experimental are immunized from liability via the "FDA exemption, "i.e. 35 U.S.C. S. 271(e)(1). The district court did not instruct the jury on the common law exemption with respect to the Merck's infringing activities. On appeal, Merck does not contend that the common law research exemption should apply to any infringing activities evaluated by the jury. Neither party has briefed this issue to this court. Moreover, during oral arguments, counsel for Merck expressly stated that the common law research exemption is not relevant to its appeal. Judge Newman's dissent, however, does not mention that the Patent Act does not include the word "experimental," let alone an experimental use exemption from infringement. See 35 U.S.C. S. 271 (2000). Nor does Judge Newman's dissent note that the judge-made doctrine is rooted in the notions of de minimis infringement better addressed by limited damages. *Embrex v. Service Engineering Corp.*, 216 F. 3d 1343, 55 USPQ2d 1161 (Fed. Cir. 2000) (Rader J., concurring); see also *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631, 14 USPQ2d 1636, 1642 (Cl. Ct. ("This court questions whether any infringing use can be de minimis. Damages for an extremely small infringing use may be de minimis, but infringement is not a question of degree.") *Deuterium* was also the decisions of Judge Rader.

It was experimental use in *Madey*, but a significant development in *Independent Service Organizations v. Xerox*⁸⁵ 203 F. 3d 1322 (Fed. Cir. 2000) which removed any anticompetitive action by a patent holder from any wrong was also not issued certiorari after the US government supported the decision of the Court of Appeals.

Experimental Use Exemption in the EC

Article 27(b) of the Community Patent Convention (CPC) has provided the basis for experimental use exception which exempts ‘acts done for experimental purposes relating to the subject matter of the patented invention. This has been adopted in nearly all the member countries of the Union⁸⁶ except Netherlands, the Patent law of which introduced the term ‘solely’ to narrow down the experiential use exemption. It says that “The exclusive right shall not extend to acts solely serving for research or the patented subject matter, including the product obtained directly as a result of using the patented process.”⁸⁷ Cornish reviewed seven major decisions in the EC and came to the conclusion that ‘the experimental use exception now has a wider purview.’⁸⁸ The seven major decisions all decided by appellate courts are

- a. *Monsanto v. Stauffer* (UK) [1985] RPC 515 (English Court of Appeal); 17 IIC 115 (1986)
- b. *Ethofumesate* (1990) GRUR 997, 22 IIC 541 (1991) (German Supreme Court)
- c. *ICI/Pharbia and Medicopharma (Atenolol)* [1993] NJ 735 (1993) GRUR Int. 887 (Dutch Supreme Court)
- d. *Kirian Amgen/Boehringer Mannheim (Erythropoietin)*, Judgment of February 3, 1994 (docket No. 93/960) (The Hague Court of Appeal). Affirmed on other grounds by the Dutch Supreme Court: [1996] NJ 462

⁸⁵ *Independent Service Organizations v. Xerox* 203 F. 3d 1322 (Fed. Cir. 2000)

⁸⁶ Belgium Patent Law 1984, Art. 28(1)(b); Denmark Patent Law, Part 3, Art 3(3), Finland Patent Law, Art. 3.3(3); France Patent Law 1968-78, Art. 30, Germany Patent Law 1981, Art. 11(2); Greece Patent Law Art 10(2)(a); Ireland Patent Act 1992, s. 42(b); Italy Patent Law Art. 1(3), Spain Patent Law Art. 52(b), Swedish Patent Law Art. 3(3), United Kingdom Patent Act 1977, s. 60(5)(b)

⁸⁷ The Netherlands Patent Law 1995, Art 53(3). The Portuguese Patent law also has similar restrictive exemptions when it says “acts carried out exclusively for testing or experimental purposes.”

⁸⁸ William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 IIC 735 (1998). Cornish further observed that “This may also follow by way of balance, from the broadening of patentable subject-matter to embrace claims to pharmaceutical substances as such, and claims to compositions for second and subsequent medical uses.” pp. 736-737

- e. *Applied Research Systems/Organon* (Follicle-Stimulating Hormone) [1996] NJ 463, 28 IIC 558 (1997); (Dutch Supreme Court, affirming a more extensive judgement of The Hague Court of Appeal, 29 IIC 702 (1998))
- f. *Klinische Versuche I* (interferon Gamma) [1995] BGHZ 130, 259; [1997] RPC 623, 28 IIC 103 (1997) (German supreme Court)
- g. *Klinische Versuche II* (Erythropoietin) [1998] RPC 423 (German Supreme Court).

An important judgment highly relevant to the submission of data for regulatory approval, that of *Upjohn*⁸⁹ was not mentioned or discussed by Cornish whereas *Ethofumesate* which had been declared as irrelevant in view of the German Patent Act amendment was unnecessarily brought in the picture.

Essentially there are three types of approaches adopted by the EC courts. The *Stauffer* case is in the UK, whereas rest of the cases are in Denmark and Germany. The Denmark case has a different implications as the wording of experimental use exception in its patent act is different from other Members of the EC.

The ECJ judgment in *Generics v. Smith, Kline & French*⁹⁰ did not address the question of experimental use exemption and submit data to the regulatory authorities as the EC Members do not have a common patent directive and the case at hand was based on the presence of the term 'solely' in the article 30(3) of the *Rijksoctrooiwet* (Netherlands Patent Law, 1910, now art. 53(3) of the ROW 1995).⁹¹ The question at the ECJ level raised by the Hoge Raad was '(1) Is a rule of national law which confers on the proprietor of a patent in respect of certain medicinal products the right to oppose, during the currency of that patent, the submission of another person of samples of the patentee medicinal products (or of medicinal products produced in accordance with the patented process) to the authority responsible for the registration of medicinal products, to be regarded as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 30 of the EC Treaty?'⁹²

⁸⁹ *Upjohn Company v. T Kerfoot & Co. Ltd* [1988] FSR 1

⁹⁰ ECJ, Case C-316/95) 41 BMLR 116; [1997] RPC 801, *Generics v. Smith, Kline & French Laboratories*

⁹¹ Article 30(3) of the ROW provides that :

'3. The exclusive right does not extend to acts undertaken solely for the purposes of an examination of the patented object, which must be taken to include a product directly obtained by means of the application of the patented process.'

⁹² *Smith Kline and French Laboratories Ltd.* , ECJ Judgement para 19

During the arguments ECJ discussed the practices and decisions of other courts but its decision was based on interpretation of Article 30 of the EC Treaty.

While trying to oppose the submissions of samples for regulatory approval, the EC Advocate General used the decision of the New Zealand Court of Appeal in *SmithKline and French Laboratories Ltd. V. Douglas Pharmaceuticals Ltd*⁹³ and in particular the observation of Hardie Boys J which said

“doubtless experimental use will usually have an ultimate commercial objective; where it ends and infringement begins must often be matter of degree. If the person concerned keeps his activities to himself, and does not more than further his knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance him in the actual market place, then he infringes, for the market place is the sole preserve of the patentee.”⁹⁴

A major weakness of the New Zealand decision was the use of *Roche Products* to narrow down the experimental use exemption on the plea that the Court was operating in an international context. The Court ignored Article 4bis of the Paris Convention that the patent act is totally territorial.⁹⁵

While discussing *Upjohn Company v. T Kerfoot & Co. Ltd*⁹⁶ where the English High Court held that the mere application for a marketing authorization in respect of a medicinal product, even when accompanied by test results, did not constitute an infringement of the patent since such submission would not amount to ‘use’ of the patent within the meaning of s. 60(1) of the Patent Act 1977, even if it is interpreted in the light of the CPC provision dealing with the experimental use exception, the Advocate General used the distinction arrived at by the Appeal Court of New Zealand in *Smith Kline v. Douglas Pharmaceuticals*. The distinction was based on the fact that in *Upjohn*, it was data which was furnished whereas the submission of sample was decided as not covered by such exception.

In France and Italy, the experimental use exceptions covered the experiments to get the approval from the regulatory authorities. In *Wellcome Found. Ltd v. Paraxel Intl. & Others*, the Paris Court of Appeal permitted experimentation use of a patented invention before marketing

⁹³ *Smith Kline and French Laboratories Ltd. V. Douglas Pharmaceuticals Ltd* [1991] FSR 522

⁹⁴ *Smith Kline and French Laboratories Ltd. V. Douglas Pharmaceuticals Ltd* [1991] FSR 522

⁹⁵ The Paris Convention, Article 4bis

⁹⁶ *Upjohn Company v. T Kerfoot & Co. Ltd* [1988] FSR 1

authorization but not after marketing authorization. The concerned medicine acyclovir was covered by a supplementary protection certificate.⁹⁷ The trial helped in determining dosages and efficacy of the active ingredient when administered using Parexel's delivery system.⁹⁸ In Italy, the Court of Milan also held that a patent holder "cannot prevent a generic manufacturer from engaging in experimental activity in connection with an application for regulatory review during the term of the patent."⁹⁹ Cornish discussed the Italian judgment to confirm that the tests were done to collect new information on side effects are justified "even if they are done in order to make submissions for product authorization."¹⁰⁰ Portugal has also interpreted its experimental use exception on similar lines although its experimental use exceptions are molded on the Dutch Patent Act.¹⁰¹

Even the European Parliament adopted a resolution to categorically introduce experimental exemption for patented products for marketing approval.¹⁰²

Australia cannot afford such hair splitting exercises. If the acts are not clear cut, they would invite enough litigations to defeat the very purpose of the act.

Experimental Use in Germany

The cases having direct relevance to the experimental use exemption in Germany are "Klinische Versuche I"¹⁰³, and "Klinische Versuche II"¹⁰⁴ this issue has been discussed by Kern¹⁰⁵ and

⁹⁷ Richard Binns and Bryan Driscoll, Are the generic companies winning the battle?, 89 *Managing Intell. Prop.* 36 (May 1999) at 38 (citing *Wellcome Found. Ltd. V. Parexel Intl. & Others* (Paris Ct. of Appeal. 1999))

⁹⁸ *Id.*

⁹⁹ Canada Patent Protection, p. 29. Canada mentioned a series of decisions in its argument in support of its Section 55.2(1). The relevant judgment was *E. R. Squibb & Sons Inc. v. Giovannia Agugginni*, 12 June 1995, T. Milano.

¹⁰⁰ Cornish, *supra* note 21, n. 57

¹⁰¹ Canada Patent Protection, p. 29. Canadian argument where Canada produced a letter from Madalene Abreu, Information Services Director, Instituto Nacional de Propriedade Industrial, to Nadene McClay, European Generic Medicines Association, 29 April 1998

¹⁰² *Id.* at 43-44 (citing No. A4-1014/96; Official J. No. C 1412, 13/05/96, p. 0063) 17. Considers that in order for the EU to be competitive in the growing European and International nonproprietary markets, measures should be introduced which enable pharmaceutical companies to begin in advance of patent or supplementary protection certificate expiry. Such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU to be available on the market immediately, but only after the expiry of a patent or supplementary certificate for a proprietary product.'

¹⁰³ Federal Supreme Court of Germany [1997] RPC 623, LEXIS UK Patent Cases 32, (BGH), 11th July, 1995, GRUR 1996, 109 – "Klinische Versuche". (Klinische Versuche Clinical Trs., 1997 R.P.C. 623 (Fed. Sup. Ct. of Germany 1995) [hereinafter *Klinische I*]

¹⁰⁴ [1998] RPC 423, Lexis UK Patent Cases 32 [hereinafter *Klinische II*]

¹⁰⁵ Michael Kern, Recent Federal Supreme Court decisions on Experimental Use and Compulsory Licensing, CASRIP Newsletter (V. 312) Europe/Germany

others.¹⁰⁶ In *Klinische I*, the defendant had developed a drug called Polyferon for treating classic rheumatoid arthritis by experimenting with human interferon resulting in an approval by the German Federal Department of Health.

The German Supreme Court defined “experiments” as any systematic action for obtaining knowledge, independent of the purpose for which the new knowledge will ultimately be used otherwise the experimental use introduces an element of finality in the experimental acts and the patented product. The experimental use thus would cover all the scientific research without any quantitative or qualitative restriction on uncovering further research results and further commercial results.¹⁰⁷ The German Supreme Court’s opinion was based on the negotiating history of Art. 31(b) of the CPC which stated that a patented invention could be used to test the possibilities of new application and further development.

The German Supreme Court also took into account that the German Constitution Art 5(3) provides for total freedom of research and limitations on property in the interest of public welfare (Art 14, The German Constitution) and will allow the patented invention to restrict the development of technology. Kern (1996) summarized the German Court’s argument in *Klinische I* by stating that “...the public interest in furthering technology demands that clinical tests and experiments remain “privileged” pursuant to Section 11(2), even if an accumulation of applications discovered by third parties whilst using the patented substance may severely encumber the patent’s exclusive exploitation.”¹⁰⁸ The German Supreme Court observed that Section 11(2) exempts all acts from the effects of a patent that are done for experimental

¹⁰⁶ Natalie M. Derzko, A Local and Comparative Analysis of the Experimental Use Exception – Is Harmonization Appropriate?, 44 IDEA1 (2003)

¹⁰⁷ *Klinische I*, at 639 “... the wording of the Act when examined naturally rather indicates that s. 11 No. 2 of the Patents Act in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use. There are then included, for example, utilization acts for experimental purposes undertaken with the subject matter of the invention in order to discover the effects of a substance or possible new uses hitherto unknown. Since the provision makes no limit, either qualitative or quantitative on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.”

Finally it noted that at p. 643

“From the viewpoint of the further technical development in the general interest, which is the aim of patent law, it is therefore appropriate to exempt clinical trials and investigations with active substances on humans as experimental rats according to the Section 11 No. 2 of the Patent act as long these experiments are directly aimed at obtaining information.”

¹⁰⁸ Michael Kern, *supra* note 100

purposes relating to the subject matter of the patented invention, “the permissibility of such experiments cannot be contingent on what the purposes they are to achieve, be they pure scientific or regulatory in nature.” The German Supreme Court rejected the argument of diminishing the economic value of the patent because of such experimental use by observing that the patent protection for further uses “does not flow from the experimental use exemption but is inherent in the patent system.”¹⁰⁹ The decision of the German Supreme Court is essentially based on the common law doctrine and it does not indulge in hair splitting exercise of when the experimental use exemptions cross the threshold of commerciality.

In *Klinische II*, the German Supreme Court dealt with the experimental use where the results from the experiments were utilized for third party submission.

The German Supreme Court Decision in *Klinische II* was between Ortho Pharmaceuticals, an exclusive licensee of Kirin-Amgen Inc. (USA) and Merck which used “rHu EPO Merck” which contains recombinant human erythropoietin as the active ingredient to conduct clinical tests. The test was done to find out whether the said product was marketable and whether it differed from the existing EPO product in a clinically relevant manner. Since the experimental acts were in the form of clinical tests, they also provided necessary data for the health authority approval as a drug. In its decision of April 17, 1997, the German Supreme Court reiterated reasons given in *Klinische I* and observed that all experimental acts are exempted irrespective of whether or not the tests produce purely scientific or predominately industrially exploitable results.¹¹⁰ It was immaterial whether the experiments were aimed at obtaining a substance approval as a drug enabling the defendant to launch this drug right after the expiration of the patent.¹¹¹

¹⁰⁹ *Id.*

¹¹⁰ *Klinische Versuche II*, 1998 R.P.C. at 431. While referring to *Clinical Trials I* case, the German Federal Supreme Court observed “The exemption is granted regardless of the purpose for which these results will ultimately be used. As the provision limits the research activities neither qualitatively nor quantitatively, it cannot make any difference whether research purposes are present beyond the current experimental purpose, nor does it matter whether the results of the experiments will serve any further purposes, industrial interests included. In order to limit the rather wide scope of the concept of experiment, Section 11 No. 2 of the Patent act requires as the scope of the exemption the deterring operating fact that the experiment must be related to the object of the patented invention. It follows from this that the object of the invention must itself be the object of the experimental activities for the purpose of obtaining the results.”

¹¹¹ *Id.* at 432

While dealing with the exemption of clinical experiments with a patented product when those experiments were exclusively or overwhelmingly carried out to obtain data for legal pharmaceutical permission, the German Federal Court observed

“According to the working of law it does not make any difference whether the experiments supply scientifically or commercially usable results or whether the test of a protected active agent achieves the aim of obtaining data for legal pharmaceutical permission, thus preparing the access to the market for after the expiration of other term of protection of the patent ...

There is also no indication that Section 11 No. 2 of the Patent Act offers a limit for the setting of commercial goals of experiments in Article 31 of the Convention for the European Patent for the Common Market of December 15, 1975 (CPC 1975 now Article 27 CPC 1989), which article corresponds word-for-word to Section 11 No. 2 of the Patent Act . . . According to this, the commercial orientation does not from the outset turn the experimental activity into an impermissible patent infringement. Something else will then have to determine when it is no longer a matter for the further elucidation of the conditions, effects, applicability, and producibility of the object of the invention, but of a clarification of commercial facts such as the needs of the market, acceptance of prices, and possibilities of distribution. However, such a case is not given here.”¹¹²

The inevitability of the commercial character of the experiments because of the high costs associated with such research was also emphasized by the German Federal Supreme Court.¹¹³

Experimental Use Exceptions in Japan

Japanese Patent Act art. 69(1) provides for the experimental use exception. It says “the effect of the patent rights shall not extend to the working of the patent right for the purposes of experiment or research.”¹¹⁴ Japanese patent law has consistently been interpreted as meant for promotion and advancement of science.¹¹⁵ However, the Japanese courts with some hiccups¹¹⁶

¹¹² Id. at 433-434

¹¹³ Id. at 437-38. The Federal Supreme Court observed “. . . clinical experiments with a genetically engineered pharmaceutical will always be based on commercial considerations.”

¹¹⁴ Tokkyoho [PatentL.], Law No. 121 of Apr. 13, 1959 (Japan), amended by Law No. 24 of Apr. 17, 2002 (Japan), art. 67(2), translated in Japanese Laws Relating to Industrial Property (Japanese Patent Office trans., 1996)

¹¹⁵ Jennifer A. Johnson, The Experimental Use Exception in Japan: A Model for U.S. Patent Law? 12 Pac. Rim. L. & Pol. 499, 513

¹¹⁶ Monsanto v. Stoffer Japan K.K. discussed in Keiji Kondo, Clinical Testing Falls into Permissible R & D Exception of Patent Infringement, 26 AIPPI Journal 290, 291 (2001) and John A. Tessensohn, Reversal of fortune-Pharmaceutical Experimental Use and Patent Infringement in Japan 4 J. Int'l Legal Stud. 1, 25-26 ()where

finally concluded that experiments to obtain regulatory approval would also qualify as experiments within art. 69(1) of the Japanese Patent Law.¹¹⁷ Any doubt was removed when the Japanese Supreme Court reached this conclusion in *Ono Pharmaceutical*.¹¹⁸

In *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd.*,¹¹⁹ the Japanese Supreme Court discussed this issue of experimental use exemption and generic drugs. Section 69(1) of the Japanese Patent Law provides exemption for "the working of the patented invention for experiment and research". Ono asserted that Kyoto Pharmaceutical is selling the drugs of same efficaciousness as the patented drug during the patent term for the purpose of obtaining data that accompany an application for the approval of manufacture under section 14 of the Pharmaceutical Affairs Law. The Japanese Supreme Court decided that the use of drugs having the technical scope of the patented invention is "working of the patented invention for experiment and research" provided in Section 69(1) of the Japanese Patent Law and would not constitute patent infringement because

- a. The Pharmaceutical Affairs Law stipulates that a prior approval by the Minister of Health and Welfare is to be obtained for the manufacture of drugs for ensuring safety, etc., and that upon carrying out various experiments, data, etc. on the experimental results must accompany an application when requesting such an approval. ... If under the Patent law such experiments are not be interpreted as "experiments" stipulated in Section 69(1) of the Patent Law and therefore such manufacture, etc. are not possible during the patent term, the third party cannot, as a result, freely exploit the invention for a substantial period of time even

the Tokyo District Court decided that obtaining regulatory approval would not qualify as technological improvement and it is commercial in character. The Nagoya High Court and Nagoya District Court in a series of cases referred to as Synthelabo cases, confirmed Monsanto I opinion. (The cases are *Synthelabo S. A. v. Toyo Pharma K.K. & Yoshindo K.K.*, *Synthelabo S. A. v. Dalto K.K. & Nihon Pharmaceutical K.K.*, *Synthelabo S. A. v. Horita Pharmceutial Synthesis K.K.*, *Synthelabo S. A. v. Malco Pharmaceutical K.K.*, and *Synthelabo S. A. v. talyo Pharmaceutical K.K.*); Thee decions brought a flood of litigations in Japan by the pharmacetucal patent hodlers. Chrisotpher Heath, The Patent Exemption for "Experimental Use" in Clinical Trials: Germany, Jpan, and the U.S. Compared, 22 AIPPI Journal 267, 274-275

¹¹⁷ *Otsuska Ppharmcetuical K.K. v. Towa Yakuhin K.K.*, Christopher Health, Japan: Patetn Act, Sec. 69 – "Procaterule", 30 IIC 454, 455 (1999) (translating a ortin of the Tokyo High court's decison in Otsuka Pharmaceutical Co. Ltd. Towa Yakuhin K.K.)

¹¹⁸ *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd*, Case No. 1998 (ju) 153 delivered on 16 April, 1999

¹¹⁹ *Ono Pharmaceuticals Co., Ltd. v. Kyoto Pharmaceutical Industries, Ltd*, Case No. 1998 (ju) 153 delivered on 16 April, 1999

after the term of the patent expires. This result is against the basis of the patent system mentioned above.

- b. ... If it is possible to exclude others from carrying out manufacture, etc. for the experiments required in applying the patent term for a substantial period of time, such extension of the patent term goes beyond what is expected under the patent law as benefits to be given to the patentee.”

Experimental use Exception in New Zealand

Experimental use exception has been discussed in a limited aspect of ‘the supply of a sample’ for regulatory approval and it was regarded as coming within the purview of the New Zealand Patent Act, Sections 70 to 76 to “make, use, ecise, and vend the said invention” while the submission of test results was agreed to as not coming within the purview of the patent rights. The disturbing aspect of the New Zealand judgment was the reliance of the judges on a judgment of the Federal Circuit in the USA in *Roche Products* which as has been discussed is in violation of the precedents of the Court of Claims whose decision was binding on the Federal Circuit. However, depending on *Frearson v. Loe*,¹²⁰ the New Zealand Appeal Court observed that “the right and the prohibitions are not as absolute as may appear, notwithstanding the final injunction that “these letters patent shall be construed in the most beneficial sense for the advantage of the patentee.””¹²¹ This case is not a pure experimental use case and it confirmed the decision in Upjohn that

“ . . what is being aimed at is commercial use. It is perfectly true that it can be said that the making of an application for a product licence could amount to a step towards a commercial use but it cannot, if any sense is to be given to these provisions, be said to an amount to an infringement.”

The weakness of the decision is that it ignored the decision of the Canadian Supreme Court in *Microchem* which had a persuasive value having come from a country within the

¹²⁰ *Freason v Loe* (1878) 9 Ch D 48, 66-67 where Jesel MR said that if there be neither using nor vending for profit, but merely bona fide experimentation, undertaken with a view to improving upon invention, it is not an infringement, for patent rights are not granted to prevent persons of ingenuity exercising their talents in a fair way. This point was highlighted by a number of speeches in the House of Lords in *Pfizer Corporation v Ministry of health* [1965] RPC 261

¹²¹ *Hardie Boys J in Smith Kline and French Laboratories Ltd v. Douglas Pharmaceuticals Ltd*, [1991] FSR 522, 11 BMLR 126 (Court of Appeal of New Zealand (1991)

Commonwealth judicial system and on the plea that it is operating in an international environment and as such it has to conform its decision to other international decisions.

The infringement was alleged to consist of the submission to the authority of data obtained either from abroad on tests carried out abroad or from tests carried out in the UK from imported triazolam imported from abroad and made up in the United Kingdom into appropriate dosage form. All the three judges extensively referred to the Roche judgement.

On the basis of the Bolar exemption in the USA, in 2002, the New Zealand Government amended New Zealand Patent Act to introduce exemption from patent infringement for third parties where the parties are making, using, exercising or vending a patented invention for purposes reasonably related to the development and submission of information required to regulatory authorities.¹²²

Experimental Use Exceptions and Canada-Patent Protection

In *Microchem v. SmithKline & French* [1972] S.C.R. 506, the Canadian Supreme Court while dealing with the alleged patent infringement observed that since the alleged patented medicines had “never entered into commerce so that no damage was suffered by plaintiff and no profits made by the said defendant as a result of these experiments”, they would not constitute infringement. While discussing the decision of Walsh J.,¹²³ the Canadian Supreme Court observed

“In my view he was in error in holding as he did that an experimental user without a licence in the course of bona fide experiments with a patented article is in law an infringer. The reasoning of Jessel M.R. in *Frearson v. Loe* ((1878), 9 Ch. D. 48) and approved by Vice-Chancellor Bristowe in *Procter v. Bayley & son* ((1889), 6 R.P.C. 106 at 109) is applicable. Jessel M.R. said at pp. 66-67:

The other point raised was a curious one, and by no means free from difficulty, and what occurred with regard to that was this, that the defendant at various times made screw blanks, as he said, not in all more than 2lbs., by various contrivances by which no doubt screw blanks were made according to the Plaintiff’s patent of 1870, as well as that of 1875;

¹²² Supra note 3

¹²³ *Smith Kline v. Microchemicals*, Exchequer Court of Canada, 60 C.P.R. 193; 1969 LEXIS 205

they seem to have been an infringement of both. He said he did this merely by way of experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in fair way. But if their be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not be considered within the meaning of the prohibition, and if it were, it is certainly not the subject for an injunction.¹²⁴

The reason Walsh J.¹²⁵ gave for regarding such experimentation as infringing was that Microchem's experiment were not carried out for the purpose of improving the process but to enable Micro to produce it commercially as soon as the license it had applied for could be obtained. The Canadian Supreme Court observed that "I cannot see that this sort of experimentation and preparation is an infringement. It appears to me to be the logical result of the right to apply for a compulsory license."¹²⁶ Canada subsequently introduced sections 55.2(1) and 55.2(2)¹²⁷ to incorporate the Canadian Supreme Court's decision in the above case in the Canadian Patent Act which became a subject of dispute between Canada and the EC before the

¹²⁴ *Microchem v. SmithKline & French* [1972] S.C.R. 506, 519

¹²⁵ *Smith Kline v. Microchemicals*, Exchequer Court of Canada, 60 C.P.R. 193; 1969 LEXIS 205

¹²⁶ *MicroChem v. SmithKline* [1972] S.C.R. 506; 1971 S.C.R. LEXIS 75, p. 520

¹²⁷ Section 55.2(1) of the Canada Patent Act – "It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product." This was interpreted by the EC as – to carry out experiments and tests required (proof of safety and bioequivalency) to obtain marketing approval of the copy of an innovative medicine before the expiration of the relevant patent in order to ensure market access immediately following the patent expiry (in particular Section 55.2(1) of the Patent Act)

Section 55.2(2) "It is not an infringement of a patent for any person who makes, construct, constructs, uses or sells a patented invention in accordance with submission (1) to make, construct or use the invention, during the applicable period provided for the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires." The EC interpreted this as -manufacture and stockpile patented products for a period of up to six months before patent expiry (in particular section 55.2(2) of the Patent act in conjunction with the 'Manufacturing and Storage of Patented Medicines Regulation' as put by the EC in Canada-Patent Protection of Pharmaceutical Products, Request for the Establishment of a Panel by the European Commission, WT/DS114/5, dated 12 November 1998

DSU and resulted in the WTO Panel decision in *Canada-Patent Protection of Pharmaceutical Products* which has been extensively discussed by Daya Shanker.¹²⁸

The above examination of a series of decisions from a number of countries where there has been no specific exemptions or a limited specific exemption as in the USA or where exemptions have been given for experimental use in general as in the UK, Germany and Japan shows that “making” in the patent acts has never been recognized either in the USA or in the EC or in Japan, the major users of patent rights as absolute and in a literal sense and that making monopoly excludes others only from the commercial market place of the patent and not from any other purpose which would not affect the commercial market place of the patent holder and his profit in the territory of the patent. When the specific exemption has been given in the domestic patent acts compatible with Article 30 of the TRIPS Agreement as in the Bolar Exemption or in the Canada Patent Act Sec. 55.(2)(1) and 55.(2)(2), there is no limit to the manufacture of the patented product if the resulting activity is meant for getting approval from any regulatory bodies to start commercial activity immediately after the expiration of the patent as has been confirmed by various judicial decisions and even by the WTO Dispute Settlement Panel in *Canada-Patent Protection*.¹²⁹

University Research and Technology Transfer

No doubt the universities are becoming a little aggressive about the ownership of the patent and this issue was discussed by Rai and Eisenberg.¹³⁰ The examples from the University of

¹²⁸ Daya Shanker, “Brazil , Pharmaceutical Industry and the WTO, *Journal of World Intellectual Property*, 2002, Vol. 5, No. 1, pp. 53-104

- ‘India, the Pharmaceutical Industry and the Validity of TRIPS, *Journal of World Intellectual Property*, 2002, Vol. 5, No. 3, pp. 315-372

-The Vienna Convention on the Law of Treaties, The dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement, *Journal of World Trade*, Vol. 36, No. 4, August 2002, pp. 721-772.

¹²⁹ Canada Patent Protection, supra note --

¹³⁰ Arti K. Rai and Rebecca S. Eisenberg, Bay-Dole Reform and the Progress of Medicines, 66 *Law and Contemporary Problems*, 289 Winter Spring 2003 (“ As for eh universities themselves, their self interest is an imperfect proxy for the overall interest, particularly given the large role played in university decision making by technology transfer professionals who are not themselves academics. From a broad institutional perspective, universities both reap the rewards of the proprietary restrictions they impose on others and also pay the costs of restrictions that others impose on them. Thus, one might imagine that universities would have some interest in maintaining the public domain. The costs and benefits do not accrue, however, to the same university constituencies. The costs are largely borne by scientists who cannot get prompt access to the property technologies they seek, while the gains from licensing revenues are much more salient to the technology transfer offices.” P. 305

Rochester¹³¹ and University of Columbia¹³² which are involved in a number of litigations suggest the new aggressiveness of the universities in the USA for patenting but in a recent survey, Henry et al found that the US universities are very selective in patenting as compared to the commercial firms.¹³³ The AUTM (Association of University Technology Managers) is another forum apparently coming from the Universities with an aggressive use of patenting monopoly. However, the purpose behind extending the patenting to the universities and similar research based institutions was to transfer the technology for product development and marketing of the product with emphasis on promotion of small industries.¹³⁴

Very few universities even in the USA are able to generate significant fund because of this reform¹³⁵ and the commercial aspect of such patenting provided other proprietary right holders to force universities to pay for their proprietary tools and treat universities on par with industries.¹³⁶

In Australia, universities obtain nearly 5% of all Australian patents as exemplified by the Australian patents filed in the USA whereas CSIRO is the assignee of the largest number of patents among individual patenting organisations (4%). Other Australian organizations have nearly 3% patents assigned to them. About 29% patents are in the inventor's own name and are not assigned to anybody.¹³⁷

¹³¹ University of Rochester v. G. D. Searle & Co., Inc. Monsanto Company and others 2004 U.S. App. LEXIS 2458 (Fed. Cir. 2004) The issue was regarding the patent scientists from the University of Rochester received regarding a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H Synthetase (PGHS-2).(US Patent 5837,479 , 1998). From a division of this application, Rochester University also obtained patent for 850 on 11 April 2000 directed to methods “for selectively inhibiting PGHS activity in a human host” by “administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to [or in] a human host in need of such treatment.” Rochester was supported by amici curiae the Regents of the University of California, the University of Texas Southwestern Medical Centre at Dallas, and the University of Texas M. D. Anderson Cancer Center, which make essentially the same points.

¹³² Genentech Inc. v. The Trustees of Columbia University of the City of New York, 3:03-cv-01603 (northern District of California). Other firms involved in this litigation are Immux Corp. and Amgen Inc., Bigen, Inc. and Abbott Bioresearch Center, Johnson and Johnson and Baxter Healthcare. The Patent No. 6,455,275 along with a series of other similar patents has been alleged to be a case of double patenting.

¹³³ Henry

¹³⁴ Bayh-Dole Act, Act of Dec. 12, 1980. Pub. L. No. 96-517, s 6(a), 94 Stat. 3015, 3019-28 (1980)(codified as amended as 35 U.S.C. ss. 200-212 (1994) The purpose of Bayh dole Act is “ to use the patent system to promote the utilization of inventions arising from federally funded research development” 35 U.S.C. s. 200

¹³⁵ D. C. Mowery et al, The growth of Patenting and Licensing by U.S. Universities : An assessment of the Effects of the Bay-Dole Act of 1980, 30 Res. Policy 99, (2001) observing that leading patents at the University of California, Stanford, and Columbia are in biotechnological area. See also Annetine C. Geljins & Samuel O. their, Medical Innovations and Institutional Interdependence: Rethinking University-Industry Connections, 287 JAMA 72, 75 (2002) (noting that Columbia medical center accounts for nearly 85% of all licensed inventions.

¹³⁶ Madey v. Duke University, Supra note --

¹³⁷ Report by CHI, supra note--

The Scope of Experimental Use for Australia

Australia has an unusually strict patenting regime at the current state of industrial and scientific development. The clear cut exemptions for regulatory approval is available only when five years extension is given for the patented product under The Intellectual Property Laws Amendment Act 1998 which amended the Australian Patent Act 1990.¹³⁸ This is similar to the provision in the EC in the case of the supplementary licenses. However, practically all the EC countries have experimental use exemptions enshrined in their patent acts.¹³⁹ The Australian patenting exemption even for regulatory approval is far stricter than those practiced in the USA.

Patenting of the Research Tools and Basic research

The interpretations arrived at by the US Federal court in Roche Products which later became a norm for other courts and sometimes courts outside the USA would hamper basic research directly.

Basic research is fundamental to further discoveries and inventions and treatment of patenting as an absolute monopoly by total exclusion of the research purposes from the patent act would lead

¹³⁸ Section 78(2) "If the Commissioner grants an extension of the term of a standard patent, the exclusive rights of the patentee after the grant of the extension are not infringed by a person exploiting

(a) a pharmaceutical substance per se that is in a substance disclosed in the complete specifications of the patent and in substance falls within the scope of the claim or claims of that specifications; or

(b)

solely for purposes in connection with:

© having a good included in the Australian Register of Therapeutic Goods, where the goods are intended for therapeutic use; or

obtaining similarly regulatory approval under a law of a foreign country or of a part of a part of a foreign country.

¹³⁹ The supplementary Protection Certificate was created by Council Regulation (EEC) No. 1768/92 and stipulates following conditions.

a. the product is protected by a patent that is in force ('basic patent');

b. the product has been granted marketing authorization pursuant to either Directive 65/65/EEC (regarding medicinal products of human use) or Directive 81/851/EEC (regarding veterinary products);

c. The product has not previously been subject to an SPC; and

d. the authorization mentioned in (b) is the first one that was required to get the product to market.

The maximum term allowed for any patent in Europe is 15 years, and the maximum term allowed for any SPC is five years.

to total suffocation of R&D in Australia. The basic research normally does not look for specific applications.¹⁴⁰

A study by the National Institute of Health (NIH) in the USA concluded that 42% of the “conceptual steps” of the ten “most important medicinal treatment,” began as a basic research.¹⁴¹ The open heart surgery, blood vessel surgery and the drug treatment of hypertension are three most important inventions in this respect.

A clear cut experimental use exception in the Australian Patent Act becomes imperative because of the recent upsurge in patenting at the basic level where DNA sequences and protein molecules and even there three dimensional structure have been patented.¹⁴² A large number of such patents are registered either as a blocking or a defensive patent.

The patenting of research tools is another important aspect of the experimental use exception.¹⁴³

The patenting of research tools brought a series of litigations in the USA. In *SIBIA Neurosciences v. Cadus Pharmaceutical Corp.*¹⁴⁴ the District Court awarded US\$ 18 million to a research patent holder as royalties on anticipated profits from discoveries made by an unlicensed defendant. This was the case where the research tool patent holder was seeking royalties under

¹⁴⁰ Joshua A. Newberg and Richard L. Dunn, Keeping Secrets in the Campus Lab: Law , Values and Rules of Engagement for Industry-University R&D Partnerships, 39 Am. Bus. L. J. 187, 192 n. 13 (2002) (“The objective of basic research is to gain more comprehensive knowledge or understanding of the subject under study, without specific applications in mind.”)

¹⁴¹ National Institute General Medical Sciences, National Institute of health, Why do Basic Research? At www.nigms.nih.gov/nes/science_ed/whydo.html.

¹⁴² Three dimensional molecular structures are patentable subject matter in the USA.. U.S. Patent No. 6,490, 588 (issued December 3, 2002) claiming “A method of searching one or more ligand compound to a target biopolymer from a three-dimensional structure database.” Other three dimensional patents are U.S. Patent No. 5,856,116 (issued Jan 5, 1999 and U.S. Patent No. 6,329,184 (issued Dec. 11, 2001) See also Alicia Russo, Patent-Protection for a three dimensional Protein ?Structure May be Within Reach, 3 No. 2 Patent Strategy and Management 1 (2002) and Ben Quarmby, 3D Molecular Structure: Patentable Subject Matter under 35 U.S.C. s. 101? Duke Journal of Law and Technology -- . The patents for three dimensional structure have been issued as “patents for methods for rational drug design using the information obtained from the three dimensional structure of a protein.” (Alicia Russo 2001) although they do not come under patentable subject matter of process, machine, manufacture, or composition of matter as Sec. 10 of the US Patent act.

¹⁴³ Michael J. Stimson, Damages of Infringement of Research Tools Patents: The Reasonableness of Reach through Royalties, 3 Stanford Technology Law Review (2003).

¹⁴⁴ *SIBIA Neurosciences v. Cadus Pharmaceutical Corp.* No. 96-1231 (S.D. Cal. Feb. 26, 1999), *re’d on other grounds Sibia Neurosciences Inc. v. Cadus Pharm. Corp.* 225 F. 3d 1349, 1352 (Fed. Cir. 2000) declared the patent invalid for obviousness. The patent claimed a “method for identifying compounds that modulate cell surface protein mediated activity”. (Patent No. 5,401,629 (issued March 28, 1995).

its patent licenses that reached through its patent rights to “royalties on profits from subsequent discoveries.”¹⁴⁵

An important example of research tool method is patenting of the polymerase chain reaction (PCR) which can generate many identical copies of genetic materials.¹⁴⁶ Roche and Perkin – Lemer hold patent rights covering various PCR methods.¹⁴⁷ The other research tool method having server effects on academic research are the patents on Taq polymerase (USP 4889818), Cre/lox vectors¹⁴⁸ and on Gateway vectors.¹⁴⁹

Experimental use exceptions are important because in the name of biological advancement even the basic tools of research have been patented. When some of the research was being done to developed, patenting i.e. monopolization to commercial use was not the incentive. However, once these tools were made available, the decision was taken to monopolize them. The monopolization did not act as any incentive to develop majority of early tools.

There have been essentially two sources of arguments. One emanating mostly from the counsel of the firms having stakes in monopolization and the other from scientists and legal scholars.

The arguments from the former have been mostly on the line that monopolization has led to development of a better research tools but when the monopolization of the research tool is linked to the patenting of the basic parameters of science, it may become virtually impossible for the Australasian science and technology to progress unless there is specific exemptions on the line of Germany and Japan, two of the industrially strong nations in the world.¹⁵⁰

Walsh et al¹⁵¹ quoted one biotechnology executive responsible for IP as saying

¹⁴⁵ See Michael A. Heller and Rebecca S. Eisenberg, Can Patents Deter Innovation? The anticommons in Biomedical Research, 280 Science 698, 699 (May 1, 1998)

¹⁴⁶ U. S. Patent Nos. 4683195 and 4683202 (issued July 28, 1987)

¹⁴⁷ Shane Baek, Do you have a license? Products licensed for PCR in Research Applications, The Scientists June 8, 1998, at 21(The article reviewed the legal battles involving the PCR patents).

¹⁴⁸ B. Sauer , Manipulation of Transgenes by site-specific recombination: Use of Cre recombinase, 225 Methods of Enzymology pp. 890-900 (1993)

¹⁴⁹ A. J. Walhout, G. F. Temple, M. A. Brasch, J. L. Hartley, M. A. Lorson, S. van den Heuvel and M. Vidal, GATEWAY Recombination Cloning: Application to the cloning of large numbers of open reading frames of ORFeomes, Methods Enzymol. 328, pp. 575-592 (2000)

¹⁵⁰ Michael B. Albert, Phyllis Genter Yoshida and Debra van Opstal, The New Innovators: Global Patenting Trends in five Sectors, Office of Technology Policy, September 1998

¹⁵¹ John P. Walsh, Ashish Arora and Wesley M. Cohen, Research Tools Patenting and Licensing and/biomedical Innovation, in W. M. Cohen and S. Merrill, eds. Patents in the Knowledge-Based Economy. Washington on DC: National Academies Press (2003)

“The patent landscape has gotten more complex in the 11 years I’ve been here. I tell the story that when I started and we were interested in assessing the third party patent situation, back then, it consisted of looking at [4 or 5 named firms]. If none, were working on it, that was the extent of due diligence. Now, it is a routine matter that when I ask for some search of third party patents, it is not unusual to get an inch or two thick printout filled with patent applications and granted patents ...In addition to dealing with patents over the end product, there are a multitude of patents, potentially related to intermediate research tools that you may be concerned with as well.”¹⁵²

Heller and Eisenberg¹⁵³ and Seide and MacLeod¹⁵⁴ discussed the case of “adrenergic receptor” which has more than 100 patents requiring license to do research in this area. Warcoin¹⁵⁵ similarly found nearly 500 patent applications of which 100 were potentially of interest. Walsh et al also discussed the case of defensive patenting and characterized it as “Oklahoma Land Rush”. Henry et al¹⁵⁶ made similar observations.

An important concern has been a restrictive assertion of licensing of patents for research tools. The implication of research tools has been both upstream i.e. use of research tools to do more basic research and downstream that is the use of research tools to produce commercial end products. The examples of research tools having upstream implications are transgenic mice such as Harvard Mouse, embryonic stem cells, cre-lox technology, innumerable patenting of gene fragments, genes, and proteins including three dimensional structure of proteins providing promising targets for small-molecule drugs (such as the COX-2 enzyme for pain, CCR5 receptor for HIV, or telomerase for cancer). Human Genome Sciences patenting of HIV receptor is a unique case where the NIH scientists who found the receptor as an important drug target but found that HGS’s latent discovery had priority. As already discussed, Rochester University’s

¹⁵² Id. p. 9

¹⁵³ Heller and Eisenberg, Can Patents Deter Innovation? The Anticommons in biomedical Research, 280 Science 698 (1998)

¹⁵⁴ R. K. Seide and J. M. MacLeod, Comment on Heller and Eisenberg, Science On Line <<http://www.sciencemag.org/feature/data/980465/seide.shl>

¹⁵⁵ J. Warcoin, Intellectual Property and Development of Products in Biotechnology, Paper presented at OECD Workshop on Generic Inventions, Intellectual Property Rights and Licensing Practices, January 24, 2003, Berlin (2002)

¹⁵⁶ M. R. Henry, M. K. Cho, M. A. Weaver and J. F. Merz, DNA Patenting and Licensing, Science 297 [23 August] 1279 (2002), M. R. Henry, M. K Cho, M. A. Weaver and J. F. Merz, A Pilot Survey on the Licensing of DNA Inventions, Journal of Law, Medicine and Ethics, 31, 442-449 (2003)

case against Searle¹⁵⁷ for COX-2 patent which includes claims on drugs that inhibit the enzyme. Fortunately, Rochester University lost the case¹⁵⁸ but the deterrence effect of such litigation on scientific investigation is incalculable.

The case of beta-carotene-enhanced rice (Golden RiceTM) is an example where at least 70 patents and 15 technical property spread over 31 institutions were involved. It took more than one year for in the international aid agency to negotiate license for the development of this innovation.¹⁵⁹ Hackett and Totten discussed the case of royalty stacking in case of the hepatitis B vaccine involving 14 patents.¹⁶⁰ In their article essentially written in favor of monopolistic industries, Walsh et al confirmed that “about half of our respondents complained about licensing costs for research tools. . .”¹⁶¹ although majority of the respondents were from large pharmaceutical companies or had stakes in patent monopolization.

The fees charged for research tools “such as using a gene for screening or a vector or microarrays-for a fee ranging from \$10,000 (US) to \$200, 000 (US).”¹⁶² The extent of royalties charged for research tools can be adumbrated on the basis of the following paragraph

“Large pharmaceutical firms have also been licensing access to genomic databases, and these database fees are often tens of millions of dollars and occasionally over \$100 million (US)(Science, 1997). In 1997, for access to its database, Incyte was reported to be charging \$10 million to Upjohn and almost \$16 million (US) to Pfizer, as well as undisclosed amounts to eight other firms. These deals also include “low single digit” royalties for use of patented genes in drug development. Four pharmaceutical firms paid between \$44 million and \$90 million each to Millennium to access their data and research tools of identifying disease genes. In 1998, Bayer agreed to a deal in which they would pay up to \$465 million to Millennium to have Millennium identify 225 new drug targets within 5 years (Malakoff and Service, 2001)”¹⁶³

The magnitude of cost has virtually eliminated major universities and medium enterprises from research in this field till they are able to develop their own “do-it-yourself” solution.¹⁶⁴ There are

¹⁵⁷ University of Rochester v. G. D. Searle & Co. 2003 U.S. Dist. LEXIS 3030

¹⁵⁸ Id.

¹⁵⁹ R. D. Kryder, S. P. Kowalski and A. F. Krattiger, The Intellectual and Technical Property Components of Pro-Vitamin A Rice (GoldenRiceTM): A Preliminary Freedom-To-Operate Review, ISAAA Brief No. 2--2000

¹⁶⁰ L. B. Hackett and J. T. Totten., Report on the United States Vaccine Industry, commissioned by the Department of Health and Human Services and prepared by Mercer Management Consulting, June 14, 1995

¹⁶¹ Walsh et al, p. 16

¹⁶² Walsh et al, p. 16

¹⁶³ Walsh et al, p. 17

¹⁶⁴ National Research Council, 1997

enough examples of restricted access to upstream discoveries because of patenting and high licensing fees charged by the patent holder.¹⁶⁵ The dispute between Promega and Roche Products¹⁶⁶ is another example of the research tools virtually blocking the research. CellPro case is a classical example in the USA where the patent developed by the public fund in John Hopkins University was so broadly interpreted after CellPro had won the case in jury decision, that CellPro went bankrupt.¹⁶⁷ It is a classical case of royalty stacking where Hopkins had licensed it to B-D, which in turn licensed to Baxter which in turn licensed to others. Harvard OncoMouse is another example where extended patent awarded to a presumably research tool developed by the Harvard University and licensed exclusively to DuPont because of certain financing by DuPont during the research has led to a series of skirmishes by DuPont with research laboratories including NIH.¹⁶⁸ However, the universities getting the grant from the NIH cannot use such tool because DuPont would make them available to them under separate agreements with the sponsor with strict conditions that universities cannot use technology in industry-sponsored research without the sponsor taking a commercial license.¹⁶⁹ The issue has taken an ugly turn when DuPont's claim constitutes "any animal with germ line disruptions that is cancer prone"¹⁷⁰ and insisted payment from Massachusetts Institute of Technology and California University. According to Andrew Neighbor, Vice Chancellor, Research, California University, "DuPont's "nonnegotiable" terms and could be twice the amount of the sponsored research contract creating an "economic burden [that] will restrict research."¹⁷¹

A recent case is that of Geron which obtained exclusive license from the Wisconsin Alumni Research Foundation (WARF) and John Hopkins University to develop a number of tissue types. However, in 2001, WARF sued Geron to be able to offer license to Geron's competitors and

¹⁶⁵ Roche's fees for the application of the technology outside of diagnostics ranged between US\$ 100,000 and US\$ 500,000 with additional royalty rate of 15%. This case was fought in Europe and Australia as well where Roche lost both the disputes.

¹⁶⁶ Promega v. Roche Products

¹⁶⁷ A. Bar-Shalom and R. Cook-Deegan, Patents and Innovation in Cancer Therapeutics: Lessons from CellPro, *Millbank Quarterly* (2002)

¹⁶⁸ In January 2000, NIH and DuPont entered into an agreement covering OncoMouse (MOU is available at <http://ott.od.nih.gov/textonly/oncomous.htm>). Before this NIH entered into another agreement with DuPont regarding licensing of cre-lox technology (MOU available at <http://ott.od.nih.gov/textonly/cre-lox.htm>).

¹⁶⁹ A. Neighbor, Presentation to the National Cancer Policy Board, Institute of Medicine, April 23 (2002).

¹⁷⁰ Eliot Marshall, DuPont ups ante on use of Harvard's OncoMouse, *Science*, May 17, 2002 v. 296, p. 1212, 13

¹⁷¹ *Id.*

managed to narrow down the license.¹⁷² The ‘targets’ is an important class of research tools which refers to any cell receptor, enzyme, or other protein involved in a disease and thus provides a promising area for drug research. Gene targets such as COX-2 enzyme patent¹⁷³ and the CCR5 HIV receptor patents along with the hepatitis C protease patent are examples which have led to a number of litigations. The patenting of BRCA1 and BRCA2 by Myriad in the USA where Myriad’s contribution to the development of the research or diagnostic tool is quite controversial is another example of restricting access of research tools. Myriad threatened Pennsylvania University with a lawsuit for performing genetic tests.¹⁷⁴

Chiron is holding more than 100 patents in 20 countries related to hepatitis C and its competitors complain that they abandoned plans to enter the field because Chiron demands too much money to access its technology.¹⁷⁵ The virus was detected by the Centers for Disease Control and Prevention who signed away most of the commercial control to Chiron for a little more than US\$ 2.2 million in 1990. Elias also reported that many companies involved in hepatitis C research are reluctant to publicly discuss Chiron’s tactics as several of them have settled their lawsuits as most of them have been sued by Chiron at one time or another.

Geron similarly has collected 56 patents related to telomerase as a potential target for cancer drugs.¹⁷⁶ Even the major pharmaceutical companies such as Bristol-Myers reported that more than 50 proteins potentially involved in cancer are beyond their purview of research because the patent holders were demanding excessive royalties or were not willing to enter into any agreement.¹⁷⁷

The patenting of research tools at the basic level has added significantly to the cost of research. In their study, Walsh et al found that “Over a third of respondents (representing all three sectors) noted that dealing with research tool patents did cause delays and add to the cost of research.”¹⁷⁸ Lanjou and Schankerman observed that biomedical patents carry a greater element of litigation costs compared to other technologies¹⁷⁹ whereas the litigation cost as a whole has

¹⁷² Walsh et al, p. 25

¹⁷³ University of Rochester v. G. D. Searle & Co. 2003 U.S. Dist. LEXIS 3030 (W. D. N. Y. 2003)

¹⁷⁴ K. Blanton, Corporate Takeover, Boston Globe (24 January 2002) Magazine

¹⁷⁵ Paul Elias, Hepatitis Drug Maker Complaints Reviewed, The Associated Press, reported in iphealth@lists.essential.org dated 5th March 2004

¹⁷⁶ Walsh et al, p. 30

¹⁷⁷ Walsh et al, p. 30

¹⁷⁸ Walsh et al, p. 31

¹⁷⁹ J. O. Lanjou and O. Schankerman, Enforcing Intellectual Property Rights, NBER Working Paper (2001)

gone up considerably.¹⁸⁰ The cost of undertaking “due diligence” to avoid future litigation has also been estimated in tens of thousands.¹⁸¹

The case of Housey Pharmaceuticals is interesting in analyzing the inhibition of research by extensive patenting through research tools. Apart from asking for a substantial sum from licensees to use its patented assays and royalty on compound discovered through these assays, Housey insisted on payment of royalties even after patents on its assays expired. This led to filing of patent misuse complaint by Bayer.¹⁸²

The material transfer agreements (MTAs) are another area spawned by the patenting of research tools. Murashige discussed this aspect as a cottage industry of drafting and negotiating MTAs which apart from placing constraints on what the recipient can do with the material, it sometimes involve ownership of resultant inventions to be transferred to transferee of the material.¹⁸³

In fact, patenting of SARS virus by CDC has been done as a defensive patenting to prevent others from monopolizing the field the way Chiron has done with hepatitis C.¹⁸⁴

Research Conflict and Private-Public Partnerships

Sometimes these firms are known to have offered research tools at a discount but it's an effect on the research and publications has generated another controversy of corruption in research.¹⁸⁵

Blumenthal has done an extensive research on such partnerships and concluded that such collaboration has led to extensive delay in publications.¹⁸⁶ Blumenthal has discussed the conflict between the traditional commitment of the biomedical researcher and of the academic institution to the welfare of patients and the financial interests created by their connection with commercial companies.¹⁸⁷ Apart from the incident such as equity holding by the University of Pennsylvania and the Director of the laboratory in which the study was being conducted was

¹⁸⁰ Walsh et al, p. 31-32

¹⁸¹ Murashige, *infra* note 182, p. 1331

¹⁸² Bayer v. Housey Pharmaceuticals, Civil Action 01-148SLR (DC Del, Oct. 2001).

¹⁸³ Kate Murashige, Patents and research_ An Uneasy Alliance, 77 *Academic Medicine* 1329, 1331 (2002)

¹⁸⁴ Paul Elias, *supra* footnote 174

¹⁸⁵ Walsh et al have mentioned some of the discounted rates by Celera, Incyte and Myriad but they did not examine this issue. P. 18-19

¹⁸⁶ D. Blumenthal, E. G. Campbell, M. S. Anderson, N. Causino and K. S. Louis, Withholding Research Results in Academic Life Sciences: Evidence from a National Survey of Faculty, *JAMA* (16 April) 277 (15), pp. 1224-8 (1997); J. G. Thursby and M. C. Thursby, *Purdue Licensing Survey: A summary of Results*, Krannert Graduate School of Management, Purdue University

¹⁸⁷ David Blumenthal, Academic-Industrial Relationships in the Life Sciences, *NEJM*, vol. 349: 2452-2459 (2003)

revealed only after the death of Jess Gelsinger in the gene therapy experiment,¹⁸⁸ the integrity of the research process through bias in the findings in the companies favor¹⁸⁹ and the reduction in the openness of communication within the research environment.¹⁹⁰ In a study by Blumenthal et al, it was found that half of surveyed executives of biomedical companies admitted that their research agreements with universities included restrictions on communicating results.¹⁹¹ The conflict of interest between the commercial firms and the laboratories and the contract research organizations became such an issue that a group of editors of medical journals issued a statement denouncing the common practice of such partnership leading even to restriction on data interpretation.¹⁹² The statement by the editors shows a very sad state of affairs where the commercialization of investigation has led to erosion of intellectual inquiry. Their statement says “As editors, we strongly oppose contractual agreement that deny investigators the right to examine the data independently or to submit a manuscript for publication without first obtaining the consent of the sponsor. Such arrangements not only erode the fabric of intellectual inquiry that has fostered so much high quality clinical research, but also made medical journals party to potential misrepresentations, since the published manuscripts may not reveal the extent to which the authors were powerless to control the conduct of a study that bears their names. ... Although we most commonly associate this behavior with pharmaceutical sponsors, research by government or other agencies may also fall victim to this form of censorship, especially if the results of such studies appear to contradict current policy.”¹⁹³

¹⁸⁸ G. Vogel, FDA moves against Penn scientist, *Science*, vol. 290: pp. 2049-2052 (2000)

¹⁸⁹ J. E. Bekelman, Y Li and C.P. Gross, Scope and impact of financial conflicts of interest in biomedical research: a Systematic review, *JAMA*: vol. 289, pp. 454-465 (2003)

¹⁹⁰ D Blumenthal, *supra* note 186, at 2456

¹⁹¹ D Blumenthal, N Causino, EG Campbell and LS Louis, Relationships between academic institutions and industry in the life sciences – and industry survey, *NEJM* vol. 334, pp. 368-373 (1996)

¹⁹² Frank Davidoff, Catherine D. Angelis, Jeffrey M. Drazen, John Hoey, Liselotte Hojgaard, Richard Horton, Sheldon Kotzin, M. Gary Nicholls, Magne Nylenna, A. John P.M. Overbek, Harold C. Sox, Martin B. Van Der Weyden, Michael S. Wilkes, Sponsorship, Authorship and Accountability, *NRJM*, vol. 345, p. 825-827, 825 (2001) (“As CROs and academic medical centers compete head to head for the opportunity to enroll patients in clinical trials, corporate sponsors have been able to dictate the terms of participation in the trial-terms that are not always in the best interests of the academic investigators, the study participants, or the advancement of generally. Investigators may have little or no input into trial design, no access to the raw data, and limited participation in data interpretation. These terms are draconian for self respecting scientists, but many have accepted them because they know that if they do not, the sponsor will find someone else who will. And, unfortunately, even when an investigator has had substantial input into trial design and data interpretation, the results of the finished trial may be buried rather than published if they are unfavorable to the sponsor’s product. Such issues are not theoretical. There have been a number of such problems, and we suspect that many more go unreported.”)(references omitted)

¹⁹³ *Id.* pp. 825-826

Some of the important reported incidents regarding conflict of interest are by Rennie¹⁹⁴ and Kahn et al.¹⁹⁵ A significant case was that of Olivieri who was sued by Apotex in Canada for publishing adverse results regarding the effect of deferiprone, a bivalent iron chelator.¹⁹⁶ The University of Toronto and the Hospital for Sick children also took action adversely against Olivieri because Apotex had withdrawn funds from them. Close financial relations between investigators and industry sponsors affect the quality and outcome of clinical studies.¹⁹⁷ In such circumstances, collaboration envisaged by certain scholars would turn out to have more adverse impact on science and innovations.

Conclusion and Discussion

There has been recent argument by Gutttag¹⁹⁸ that because filing for patents have remained quite high in spite of “patent coverage on various technologies especially biotechnologies ...” The number of filing of patents does not reflect the impediments. The patent has risen because of a number of factors such as defensive patenting,¹⁹⁹ dilution of patenting criteria and extensive expansion of the patentable subject matter.²⁰⁰

In spite of the existing presence of exemptions from patent infringement in Europe of ‘acts done privately and for non-commercial purposes’ and ‘acts done for experimental purposes’ (Community Patent Convention 1975, Art 31(a), (b)), there is enough confusion for Royal Society to recommend that “governments consider clarifying and harmonizing the existing exceptions for ‘private and non-commercial’ and ‘experimental’ use.”²⁰¹

The experimental use exception is to be codified keeping in context the role of the patent to promote innovation and technology for public welfare and not to encourage monopoly. The only

¹⁹⁴ D. Rennie, Thyroid Storm, JAMA, 277, pp. 1238-43 (1997)

¹⁹⁵ J. O. Kahn, D. W. Cheng, K. Mayer, H. Murray, and S. Lagakos, Evaluation of HIV-1 immunogen, an immunologic modifier, administered to patients infected with HIV having 300 to 549X10 to power 6 /L CD4 cell count s: a randomized control trial, JAMA, 284, pp. 2193-202, (2000)

¹⁹⁶ David G. Nathan and David J. Weatherall, Academic Freedom in Clinical Research, 347 NEJM 1368 (2002)

¹⁹⁷ Elizabeth A. Boyd, Michael K. Cho and Lisa A. Bero, Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators, 78 Academic Medicine 769 (2003), L. Bero and D. Rennie, Influences on the quality of published drug studies, 12 Int J Technol Assess Health Care, pp. 209-237 (1996), T. Bodenheimer, Uneasy alliance: clinical investigators and the pharmaceutical industry, 342 NEJM, pp. 1539-44 (2000)

¹⁹⁸ Eric W. Gutttag, Immunizing University Research from Patent Infringement: The Implications of Madey v. Duke, 15 Journal of the Association of the University Technology Manager, (2003)

¹⁹⁹ Wegner and Maeribus, Walsh et al,

²⁰⁰ James Besson and Robert M. Hunt, An Empirical Look at Software Patents, March 2004, Merges

²⁰¹ Royal Society Working Group on Intellectual Property, Keeping Science Open: The Effects of Intellectual Property Policy on the conduct of Science, April 2003, p. 11

limitation Australia would have while formulating such law would be its international obligations and the practices being followed in other countries would be useful as providing subsequent practice in interpretation of those international provisions. Some of the most technologically advanced countries such as Japan and Germany have well prescribed experimental use exemptions in their patent acts and which has been consolidated through a number of judicial decisions of their highest courts. While the US law has given selective exemptions to patent for experimental use but the purpose of codifying a law is to avoid any uncertainty through litigations in the scale and scope of the experimental use exemptions.

COMMENTS

Question 1 (a) What is your understanding of current law on an experimental use exemption in Australia?

(b) What is the basis of its understanding and how certain you are of it?

© How has your understanding affected your research and development behavior?

Ans. (a) The experimental use exemption in Australia would be covered by common law exception as was done in the case of the USA before Roche Products.²⁰² Any use of patented invention which is used for testing the validity of the patent and which is used for improvement would not amount to infringement of a patent. The use of patent to generate data for regulatory approval also would not be considered as patent infringement. IN fact, any activity that does not hurt the commercial interest of the patent during the patenting period would not invite any infringement action. However, in view of the Australian Patent Act Amendment in 1998 which permitted use of patented product during the extension period to obtain data for marketing approval can be argued as excluding such action during the normal patenting period but the discussion of case in New Zealand and Canada confirms that any test during the period of patent to generate data for marketing approval would not invite infringement action.

However, the aggressiveness with which firms are taking action against research and educational institutions, it is important that experimental use exceptions should be properly included in the

²⁰² Byam v Bullford (1 Curt. 100, 4F Cas. 934 (C.C.D. Mass. 1852 NO. 2262)) supra note 1

Australian Patent Act with suitable examples to avoid litigation to encourage R&D in the universities. Any sword of litigation or penalty would push the Australian R&D behind.

(b) My understanding is based on a number of judicial decisions in the USA, UK, Germany, Japan, New Zealand and Canada along with the analysis of the TRIPS related dispute in World Trade Organization. It is also based on a review of literature relating to the experimental use exception. In case of New Zealand this fact has been made exclusively clear that the monopoly acquired through patent is not absolute and only limitation is the damage to the market place of the patent holder.

© I have used these decisions in case of issue of export of patented product to the countries not capable of manufacturing such products. There is no limitation on the amount of manufacture of such products in the exporting country if it does not affect the commercial market place of the patent holder in the territory of the patent.²⁰³

Q. What lessons if any, do overseas experience an law hold for an experimental use exemption in Australia? In particular, are any of overseas approaches to be preferred for Australia?

Ans. Every county has its own approach to experimental use exemption both as an exemption for advancement of knowledge as well as using it to generate data for submission to regulatory approval. Even in the case of the EC, where member courtiers have nearly uniform exemption under Article 27 of the Community Patent Convention with the exception of Netherlands and Portugal, the interpretations are quite different as is evident from the Federal Supreme Court of Germany's decisions in *Klinsche I* and *Klinishce II* and the decision of the Appeal Court in *Monsanto v. Stafford* in the UK.

Australia would have to draft its own experimental use exemption law depending upon it's needs and requirements including the encouragement of research in the universities and other research institutions. The most important aspect of the common law principle is that the use of the patent whether experimental or otherwise should not hurt directly the market place of the patent holder in the territory of the patent.

²⁰³ Daya Shanker, Para 6 solution of the Doha Declaration, Article 30 of TRIPS and Non-Prohibition of Exports under the TRIPS Agreement, Working Paper , (Forthcoming)

The scope and scale of exemption should be limited by only the international agreements Australia has entered into and the public policy behind granting of these monopolies for generating innovation. It should not be seen as conforming to the wishes of the monopolistic industries which always try to promote the cause of monopoly.

Only limitation would be Article 30 of the TRIPS agreement which says

‘Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’

The exceptions are not

- a. to conflict unreasonably with the normal exploitation of the patent
- b. do not prejudice the legitimate interests of the patent owner, and
- c. it should take into account the legitimate interests of the third parties.

The practices followed in other countries would be termed as a form of subsequent practice under Article 31(3) (b) of the Vienna Convention. Australia must prepare its own laws on experimental use exception depending on its requirements.

Q. 3 What are the constraints for an experimental use exemption (or possible alternatives) under any of the international agreements to which Australia is a signatory?

Ans. I have briefly discussed the constraints mentioned in Article 30 of the TRIPS Agreement. Here I will discuss in detail the developments. One important aspect is that the Panel report in Canada-Patent Protection²⁰⁴ is binding only on the parties concerned although this report does have a value as *acquis*. The Panel Report was not regarded as a genuine dispute by a number of authors including myself. It was more of an attempt to nullify the decision of the German Supreme Court in *Klinische I* and *Klinische II* permitting use of patented products to generate data for submission to regulatory authorities. The panel report had a number of weaknesses. The important ones are that the panel in Canada-Patent protection tried to eliminate the role of object and purpose from the interpretations of the provisions of the TRIPS Agreement when it agreed with the EC that object and purpose are not only subordinate to certain specific provisions of the

²⁰⁴ Canada-Patent Protection, *supra* note

TRIPS Agreement but they are irrelevant as far as interpretation of the TRIPS Agreement is concerned.²⁰⁵ This observation of the Panel was subsequently removed through the Doha Declaration on Public Health.

History of experimental use exceptions in the TRIPS Agreement in relation to Article 30 of the TRIPS Agreement was provided in Annex 6 of Canada –Patent Protection²⁰⁶ by the Secretariat for the Panel. The Composite Draft Text dated 12th June 1990 on the basis of five drafts submitted by the EC,²⁰⁷ the USA,²⁰⁸ Switzerland,²⁰⁹ and 15 developing countries²¹⁰ says

Composite Draft Text (Informal Note No. 1404 of 12 June 1990)

Para III. 5.3.2

‘Exceptions to rights Conferred

‘Limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as rights based on prior use, acts done privately and for non-commercial purposes and acts done for experimental purposes, provided that the take into account the legitimate interests of the proprietor of the patent and of third parties.’

The chair issued a revised text on 23 July 1990²¹¹ with slight modification.

Section III. 5.3.2

Exceptions to Rights Conferred

‘2.2 [provided that legitimate interests of the proprietors of the patent and of third parties are taken into account,] limited exception to the exclusive rights conferred by a patent may be made for certain acts, such as:

2.2.2 Acts done privately and for non-commercial purposes

2.2.3 Acts done for experimental purposes’

Both these drafts were based on the European Communities draft TRIPS Agreement (MTN.GNG/NG11/W/68) as other draft agreements did not have such corresponding provision.

²⁰⁵ Canada-Patent Protection, para 7.92. Daya Shanker discussed the weaknesses in the panel report. (Daya Shanker, The Vienna convention on the Law of Treaties, the dispute Settlement System of the WTO and the Doha Declaration on the TRIPS Agreement, 36 Journal of World Trade 715, 742 (2002)

²⁰⁶ Canada Patent Protection, Annex 6

²⁰⁷ Draft Agreement on Trade Related Aspects of Intellectual Property Rights, GATT Doc. MTN.GTG/NG11/W68 dated 29th March 1990-Negotiating Group on Trade Related Aspects of Intellectual Property Rights including Trade in Counterfeiting Goods Received from the European Commission

²⁰⁸ GATT Doc. MTN.GNG/NG 11/70 dated 11th May. Communication from the United States

²⁰⁹ GATT Doc. MTN.GNG/NG 11/W/74 dated 15th May

²¹⁰ Annex. GATT Doc. MTN.GNG/NG 11/71 dated 14th May

²¹¹ Chairman’s Text of 23 July 1990, Doc. MTN.GNG/NG11/W/76 of 23 July 1990

However, in the subsequent texts the specific mention of the items to be excluded were removed till it went to the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations of 20 December 1991. The term “Parties” was changed to “Members”, in the TRIPS Agreement Article 30. The brief history shows that the EC in the Draft Final Act, 1991 tried to put the Community Patent Convention not accepted even at that time by all the Members of the EC as part of its draft but that was not accepted and the TRIPS Agreement covered a much wider field than suggested by the EC.

As such Australia would have full freedom to include an experimental use exception except that these exceptions should not prejudice the market place of the patent holder during the period of patent in the territory of the patent.

Q. 4 Is there any empirical evidence that the balance between the incentives for innovation and the ability to use innovations, particularly for research and development, is being significantly affected by the absence of an explicit experimental use exemption (or some other provision) in Australia patent law?

This is a very difficult question. In fact there is no empirical support even to suggest that patent leads to innovation. The patenting right from the beginning has been regarded as a temporary monopoly granted to inventors to bring his invention in the open through written description requirements. Maskus²¹² has discussed this aspect along with few others but I have not come across any empirical or theoretical support saying that monopoly can promote innovation. Although there have been some articles essentially from the World Bank which normally reflects the interests of certain sections, there is no empirical support for the view that strong IPR leads to more innovation.²¹³ A number of authors have used growth theories to argue Schumpeterian need for monopoly to innovate. Arrow²¹⁴ is normally quoted along with Shell²¹⁵ that only those

²¹² Keith Maskus, Intellectual Property rights in the global Economy, the Institute for International Economics, (2000). Chapter 3 Globalization and the Economics of Intellectual Property rights: Dancing the Dual distortion, p. 27

²¹³ Keith Maskus and Christine McDaniel, Impacts of the Japanese Patent System on Productivity Growth, Japan and the World Economy, Vol. 11, pp. 557-574 (1999); Water G. Park and Juan Carlos Ginarte, Intellectual Property Rights and economic Growth, Contemporary Economic Policy, vol. 15, no. 3, pp. 51-61; Primo Braga Carlos, Carsten find and Claudia Paz. Sepulveda, Intellectual property Rights an Economic Development, World Bank Discussion Paper No, 412 (2000)

²¹⁴ K. J. Arrow, Economic Welfare and the Allocation of Resources for Invention, in Richard Nelson (ed.) The Rate and Direction of Inventive Activity, Princeton , NJ: Princeton University Press (1962)

economic models departing from twin assumptions of decreasing returns to scale and perfect competition were able to show persistent growth and endogenous technological progress. Arrow argued that a free enterprise economy may lead to underinvestment in invention and research because it is risky, because the product can be appropriated only to a limited extent, and because of increasing returns in use although his main emphasis was on uncertainty. The question of inappropriability that is the diversion between social and private benefits can only be answered by well-defined property rights. The third issue is that of indivisibility where the act of invention involves a substantial upfront expenditure of time and money to produce one formula, or book but thereafter copies can be made at a fraction of the cost. Economists call it indivisibilities which result in dramatically increasing returns to scale. The close connection between the innovative activity and the monopoly rights have been discussed by a number of scholars.²¹⁶

According to the scholars, in a free market economy having pricing at marginal cost would not cover huge initial cost necessary to create the prototype as there will be no incentive for inventors to bring their inventions to reality. This problem appears to have been solved by the normal model of monopolistic competition developed by Dixit and Stiglitz.²¹⁷

The underlying assumption is that economic growth requires technological change, implying increasing returns which means imperfect competition. Romer formalized this approach through his “theory of endogenous growth” using new terminology. He refined the ideas of Arrow and others. Robert Lucas at this time came up with his ideas of importance of human capital to economic growth. Around this time, Paul Krugman and Elhanan Helpman and others used increasing returns theory with international trade economics creating “new trade theory.” Similar theories became basis for industrial organization economics.

²¹⁵ K. Shell, Toward a Theory of Inventive Activity and Capital Accumulation, *The American Economic Review* (papers and Proceedings), 56, 62-68, (1966) Shell also observed ““For the economy in which technical knowledge is a commodity, the basic premises of classical welfare economics are violated, and the optimality of the competitive mechanism is not assured.” (Shell, 1967, p. 68, K. Shell, A Model of Inventive Activity and Capital Accumulation” in *Essays on the Theory of Optimal Economic Growth* (K. Shell, ed.) Cambridge, Massachusetts: MIT Press, 67 -85

²¹⁶ See P. Aghion and P. Howitt, A Model of Growth through Creative Destruction, 60 *Econometrica*, 323-351, (1992); G. M. Grossman and E. Helpman , Quality Ladders in the theory of Growth, 58 *Review of Economic Studies*, 43-61 and Romer.

²¹⁷ A. K. Dixit and J. E. Stiglitz, Monopolistic competition and Optimum Product Diversity, 67 *American Economic Review*, , pp. 297-308, (1977)

The idea of nonrivalry is central to Romer's theory of endogenous growth. In fact Romer went to the extent that endogenous innovation and growth is impossible under competitive conditions.²¹⁸

The nonrivalry nature of the idea is based on the concept of fixed cost that is once the idea exists, they can be freely appropriated by other entrepreneurs. This is essentially based on Shell's fundamental assumption underlying the increasing returns-monopolistic competition. However, Boldrin and Levine argued that "Only ideas embodied in people, machines or goods have economic value."²¹⁹

Boldrin and Levine argued that it is not the fixed costs but the sunk costs which leads to endogenous economic innovation. Boldrin and Levine on line with Hellwig and Irmen²²⁰ argued that "if the innovator has unique access to a strictly diminishing return technology and does not take advantage of his monopoly over production, never-the-less innovation will occur"²²¹ but Boldrin and Levine did not agree with Hellwig and Irmen that ideas show some delayed spill over without cost. Romer called appropriability as excludability. Romer argued that appropriability has no bearing on the shape of the feasible technology set. Boldrin and Levine strongly argued that the government enforced monopoly may increase the payoff to the original innovator, it reduces the incentive for future innovation and as such indivisibility will lead to less innovation and reduce the incentive for innovation. Scotchmer²²² also argued on similar line. An idea originally propounded by Rosen²²³ as how more efficient technologies for the reproduction of ideas can provide large rent to superstars even in the absence of monopoly.

A very important analysis of Boldrin and Levine has been that government grants of monopoly power are more prone to lead to "socially costly rent-seeking behavior than to foster innovation and growth."²²⁴ and that the patent office is as prone to regulatory capture as any other government agency. The report of the Federal Trade Commission is quite relevant where it observed that patent holders cannot be customers of the US patent office. Although Lamoreaux

²¹⁸ See P. M. Romer, Are Nonconvexities Important for Understanding Growth? 80 *The American Economic Review* (Papers and Proceedings), 97-103 (1990); P. M. Romer, Increasing Returns and Long Run Growth, 94, *Journal of Political Economy*, 1002-1037 (1986); P. M. Romer, Endogenous Technological Change, 98 *Journal of Political Economy*, S71-S102 (1990)

²¹⁹ See Michele Boldrin and David K. Levine, Perfectly Competitive Innovation, Research Department Staff Report 303, Federal Reserve Bank of Minneapolis, March 2002, [hereinafter Boldrin and Levine], p. 6

²²⁰ See M. Hellwig and A. Irmen, Endogenous Technological Change in a Competitive Economy, 101 *Journal of Economic Theory*, 1-39 (2001)

²²¹ See Boldrin and Levine, supra note 218, p. 3

²²² S. Scotchmer, Standing on the Shoulders of Giants, 5 *Journal of Economic Perspective*, (1991)

²²³ S. Rosen, The Economics of Superstars, *The American Economic Review* 71, 845-858 (1981)

²²⁴ Boldrin and Levine, supra note 218, p. 4

and Sokoloff²²⁵ in their bid to suggest that patenting leads to innovation argued that the change in the patent system in 1836 in the USA led to the exposition of the innovation but the change had actually made it difficult to patent as it established scrutiny by the technical experts. Tofuno²²⁶ had discussed the extraordinary growth in innovations in the financial industry under a competitive environment. The fact that innovation came down with the extension of property rights to the information sector is evident from the study of James Bessen.²²⁷ Schroth and Herrera (2001) empirically demonstrated that despite the absence of patent and copyright protection an extremely rapid progress of new securities, the dominant innovators maintained higher market share. Boldrin and Levine also argued that an entrepreneur attempting to reproduce his existing capital of quality when the same capital can be used to introduce capital $i+1$ would suffer a loss at equilibrium prices. In this sense, the cooperative pressure from other entrepreneurs forces each one to innovate in order to avoid a loss. Sunk costs unlike fixed costs poses no particular problem for competition but it is only the indivisibility involved in the creation of new ideas that can affect the allocational efficiency of competitive prices. It is only the rent accruing to the fixed factors comprising the creation of new ideas should cover the initial production cost.

An important aspect discussed by Boldrin and Levine is that of innovations built on past innovations as emphasized by Scotchmer.²²⁸ The generation of simultaneous ideas using the previous creations makes the concept of indivisibility irrelevant. Fishman and Rob²²⁹ have discussed the role of durability in reducing the incentive to innovate. The simple theory is that a monopolist would not choose to innovate because any diversion of fund would reduce current-period revenue below the maximum, while it cannot raise revenue in any future period.

Normally, in a monopoly the loss is calculated as a deadweight loss. But monopoly produces “collateral damages” in a number of other ways and some of these damages are much more than

²²⁵ N. Lamoreaux and K. Sokoloff, *Intermediaries in the U.S. Market for Technology: 1870-1920*, NBER working Paper 9017, (2002)

²²⁶ P. Tofuno, *First Mover Advantage in Financial Innovation*, 3 *Journal of Financial Economics*, 350-370 (1989)

²²⁷ James Bessen and Eric Maskin, *Sequential Innovation, Patents and Imitation*, MIT Department of Economics Working Paper 00-01, Harvard University and MIT, 2001, James Bessen, *Specialization and the Innovation of Complex Technologies*, Working Paper No. 2, MIT (2000)

²²⁸ S. Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Laws*, 5 *Journal of Economic Perspective*, (1991)

²²⁹ A. Fishman and R. Rob “Product Innovation by a Durable Goods Monopoly”, 31 *Rand Journal of Economics* 237-252 (2000)

deadweight losses. These damages range from rent seeking, manipulation of the political and legal systems as well as suppression of the subsequent innovation through preventing cumulative innovation.

A clear example has been given by Judge Newman in her dissent in *Integra Life Sciences v. Merck*²³⁰ where she observed

“Were all research using RGD peptides prohibited until the *Integra/Telios* patents expired, not even the patent owner would benefit, for the patented products had failed in *Telio’s* hands, leaving the patentees valueless until *Scripps* and *Merck* made their discoveries as the cyclic peptides and their anti-angiogenic properties. The panel majority states that because the *Scripps/Merck* research had the goal or hope -----.”²³¹

The growth of patenting in Australia is a recent phenomenon and considering the level of research at present pursued in Australian Universities and technical institutions as reflected in CHI Report, the patenting monopoly may not have been an issue but when items developed with the use of patentable inventions become a market success, invariably a number of claims are bound to occur. This is what happening in the USA and other countries.

Q. 5 Are there any overwhelming arguments for consideration of pre-grant conditions for patents as a complement or alternative to an experimental use exemption under Australian law?

Ans. This is a very crucial question. The extraordinarily growth in patentable subject matter particularly in the USA followed by other countries has led to a need for a wide application of experimental use exception. The growth in the patentable subject matter in the case of biotechnology and the computer software and business methods are classical examples. The case of biotechnology is the patenting of DNA sequences and even those sequences the utility of which is still not known. The patenting of DNA and its sequences started from patenting of life forms²³² and has gone to the extent of patenting of human genomes and genomes of any other

²³⁰ *Integra Life Sciences v. Merck*, 331 F. 3d 860, 877 (Fed. Cir. 2003)

²³¹ *Id.*

²³² *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

Diamond v. Diehr, 450 U.S. 175 (1981) (“.. I order to determine its meaning we may not be unmindful of the Committee Reports accompanying the 1952 Act which informs us that Congress intended statutory subject matter to “include anything under the sun that is made m by man.” S. Rep. No. 1979, 82 Congress. 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82nd Cong. .2d Sess., 6 (1952)”p. 187

virus, bacteria and animal although such patenting does not show applicability or utility.²³³ The patenting of human genome has become a controversial issue but with the help of Court of Appeals in Amgen²³⁴ and the United States Patent and Trademark Office,²³⁵ the patenting of nucleotide sequences has picked up quite fast. The trend has been followed in the EC through the Biotechnological Directive²³⁶ enjoining patenting of similar nature. There has been a newspaper report that some Australian company has patented a large number of EST as research tools. The trend has been picked up in other countries such as Japan which has started massive projects identifying therapeutically important proteins. The factory like approach of Japan's 'Protein 3000' programme and the US Protein Structure Initiative is able to determine the structure of thousands of proteins. Because of an agreement reached in November 2002 between Japan, the EC and the United States, there is no claim for a patent on structural data but the data from the Japanese Programme will be made available through partnerships to companies in Japan before they are released internationally.²³⁷ In 2001, British Biotechnology company Oxford Glycosciences (OGS) announced attempt to patent more than 4,000 proteins linked to diseases.²³⁸

Other areas showing geometrical growth in patenting are patenting of computer programs and business methods. This opened a floodgate of patenting in the USA and led to collapse of a large

²³³ E. Richard Gold, SARS genome patent: Symptom or Disease? *The Lancet* 361 June 14, 2003 pp. 2002-2003, 2002 ("Recent news that researchers in the USA, Canada, and Hong Kong have applied for patents covering the SARS genome illustrates how the patent system is still not yet ready for the breakout of genomic patent claims. IN particular, the news demonstrates that the patent seems to be adjusted-not discarded-by governments to better reach the goal of that system: the attainment of the public good.")

²³⁴ *Amgen v. Chugai Pharmaceutical Co.* 13 USPQ 2d 1737, 1759 (D. Mass, 1989), upholding the validity of claims of U.S. Patent 4,703,008 to purified and isolated human DNA sequences.

²³⁵ United States Patent and Trademark Office, Department of Commerce, Utility Examination Guidelines, Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices, p. 1092-93 where the USPTO justified the patenting of genes and DNA on the basis of the presence of the term discoveries in the US Constitution dealing with the intellectual property rights. The patenting of natural products doctrine was justified on a few of the decisions in violation of the US Supreme Court's decisions in *Cochrane v. Badische Anilin*, 111 U.S. 293, 4 S. Ct. 455 (1884) and *American Wood Paper v. Fibre Disintegrating Co.*, 90 U.S. 566 23 Wall. 566 and other related decisions. It also ignored a number of decisions in *In re Fisher*, 50 CCPA 1025; 307 F.2d 948 (1962), *In re Seaborg*, 51 CCPA 1109; 328 F.2d 996 (1964), *In re Marden*, 18 CCPA 1057; 47 F.2d 958 (1931), *In re Mertz*, 25 CCPA 1314; 97 F.2d 599, *General Electric v. De Forest Radio*, 28 F.2d 641 and others. It has recently been discussed extensively by John M. Conley and Robert Makowski, Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (part I) 85 *Journal of the Patent and Trademark Office Society* 301 (2003) and Daya Shanker, Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System (forthcoming).

²³⁶ European Biotechnological Directive

²³⁷ David Cyranoski, Intellectual Property: This Property belongs to ..., *Nature* 426, 10-11 (6th November 2003)

²³⁸ *Id.*

number of companies. The patenting of the computer programs was attributed to the Federal Court of Appeals decision in *State Street* but is essentially on the direction of the US government.²³⁹ In *Parker v. Flook*,²⁴⁰ the US government opposed the patenting of computer programs on the basis that patenting of computer programs would stifle innovations. However, it introduced patenting of computer programs through deletion of a paragraph of s. 706.03(a) from the Manual of Patent Examining Procedures (MPEP). The paragraph said

“Though seemingly within the category of process or method, a method of doing business can be rejected as not being within the statutory classes. See *Hotel Security Checking Co. v. Lorraine Co.* 160 F. 467 (2nd Circuit 1908) and *In re Wait*, 73 F. 2d 982, 24 U.S.P.Q. (BNA) 88, 22 C.C.P.A. 822 (1934). (MPEP s. 706.03(a)(1994).”

The deletion of this paragraph and the introduction of another paragraph in the US Patent and Trademark 1996 Examination Guidelines for Computer Related Inventions requiring the claims for methods of doing business should be treated like any other process claim was picked up by the US Court of Appeals for the Federal Circuit²⁴¹ The patentability of the computer software has become a grave issue in the EC with opposition from a large number of organizations including the European Parliament.²⁴² The European Patent Office was under pressure to rescind “computer program exception” but the relaxation of business method patent was not on the agenda.²⁴³ However, in a juridical coup, the President of the EPO making a preemption of the political decision to be taken by the European governments decreed a regulation that patent claims to computer programs and business methods by introducing changes in the Guidelines of the Patent in the EPO.²⁴⁴ A computer program is to be known as a “computer implemented invention” and a computer system suitably programmed for use in the field of business and economy is to be known as an invention within the meaning of Article 52(1) of the EPC. Bessen

²³⁹ *State Street Bank & Trust Co. v. Signature Financial Corp.* 149 F. 3d 1368 (Fed. Cir. 1998).

²⁴⁰ *Parke v. Flook* 437 U.S. 584 (1978) (“The acting Commissioner of Patents and Trademark filed a petition for a writ of certiorari, urging that the decision of the Court of Customs and Patent Appeals will have a debilitating effect on the rapidly expanding computer “software” industry and will require him to process thousands additional patent applicants. Because of the importance of the question, we granted certiorari, p. 491)

²⁴¹ *State Street Bank & Trust Co. v. Signature Financial Corp.* 149 F. 3d 1368, 1377 (Fed. Cir. 1998).

²⁴² Daya Shanker, India, the Pharmaceutical Industry and the Validity of TRIPS, 5 *Journal of World Intellectual Property* 315, 321-325 (2002)

²⁴³ Michal Likhovski, Michael Spence and Michael Molineux, *The First Mover Monopoly; A Study on Patenting Business Methods in Europe*, Olswang and Oxford Intellectual Property Research Centre, Oxford University (2001)

²⁴⁴ European Patent Office, *Guidelines for Examination in the EPO, Part C, Chapter IV, 2, Inventions* available at http://www.European-patent-office.org/legal/gui_lines/e/e_iv_2.htm (2001)

and Maskin²⁴⁵ and Barton (quoted in Lemley)²⁴⁶ such patents have tendency to inhibit innovation in software field.

Bessen and Hunt recently analyzed software patenting and concluded that the software patents since 1998 have grown so fast that they now comprise 15 percent of all patents.²⁴⁷ The software patents are normally acquired by large manufacturing firms and less than 5 per cent belong to software publishers. The enormous increase in patenting is not explained by changes in R&D investments, employment of compute programmers, or productivity growth. The patenting is strategic in nature and does not reconcile with the traditional innovative theory of patents. Brownyn Hall also came with similar arguments regarding inhibitory effect of patent expansion to softwares and business methods because of the incremental nature of such innovations.

Q. 6 Does fair dealing (or fair use) in copyright law hold any lessons for “experimental use” in Australian patent law? For example, could any of the provisions for fair dealings/use be translated into an experimental use in provision in patent law? Or do differences in the nature of and application of copyright and patent rights limit the analogies between the two systems?

Ans. Fair dealing or fair use was also a creation of Justice Story in *Folsom v. Marsh*, 9 Fed. Cas. 342, F. Cas. No. 4901 (C.C.D. Mass. 1841) (No. 4901). While discussing the Bolar Exemption²⁴⁸ the US House Report drew this analogy stating “Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.”

The US House Report displays two aspects of role of fair dealing. One is experimental use is a form of fair dealing and second that such fair dealing does not distinguish between commercial and non-commercial aspects of experimental use. As has been mentioned in the Issue Paper²⁴⁹ the traditional assumption behind efficient licensing of patents has broken down where patent is obtained in an offensive and a defensive manner. This aspect has also been clearly dealt with by

²⁴⁵ James Bessen and Eric Maskin, *Sequential Innovation, Patents and Imitation*, Working paper No. 00-01, Department of Economics, MIT, Cambridge, Massachusetts, (2000) ;

²⁴⁶ Mark A. Lemley, *Preconceiving Patent in an Age of Venture Capital*, 4 J. Small and Emerging Business L. 137 (1999)

²⁴⁷ James Bessen and Robert Hunt, *An Empirical Look at Software Patents*, Working Paper, Boston School of Law, March 2004

²⁴⁸ 35 U.S.C. 271(e)(1),

²⁴⁹ Patent and Experimental Use, Issues Paper, Advisory Council on Intellectual Property, p. 11, February 2004

O'Rourke.²⁵⁰ It is a very strong argument and should be clearly brought out as a supplementary in any proposed amendment if any of the experimental use.

Q. 7 do basic, applied or hybrid researches have different needs with respect to the patent system? If so, how can the patent system accommodate these differences?

Ans. I do not think so. The experimental use exemption is to promote the advancement of science and innovation and irrespective of the field, if it serves the public purpose, it should be promoted. Any amendment of the Australian Patent Act in this regard should strive to remove any confusion and uncertainty in the interpretation. Only limiting factor would be the direct harm done to the patent holder in his market place although patentees have also tried to include the harm done even after the patent expires. However, such harm has not been accepted to either in the USA or by the WTO Panel in Canada- Patent Protection.

It is also difficult to agree with Merger's argument that the jump from lab result to commercial product was much shorter than it had been in the past.²⁵¹ The trend started by the US PTO to start patenting EST and computer softwares point out the dilution of the patenting criteria. The use of venture capital is also disputable. The extension of patenting to softwares after State Street²⁵² led to total withdrawal of venture capital from the software industry. The decision in State Street is also noteworthy because of the assertion of judge Rich that there need not be any invention for claiming the monopoly.²⁵³ Similarly, with the exception of certain firms like Incyte, Human Genome etc. there appears to be not too much venture capital success in biotechnology. According to Ernst and Young (New York City) in 1999, the US biotechnology industry lost US\$ 5.1 billion on revenue of US\$ 18.6 billion. During that period, only 23 of the hundreds of companies were profitable.²⁵⁴ The question of public spending on innovation is also disputable. The NIH budget has grown by 48% since 1998 and stood at \$20.3 billion in 2000.²⁵⁵ The

²⁵⁰ Maureen O'Rourke, Toward a Doctrine in Patent Law, 100 Columbia Law Review 1177 (2000)

²⁵¹ Merger

²⁵² State Street Bank & Trust Co. v. Signature Financial Group, Inc. 149 F.3d 1368 (Fed. Cir. 1998), Cert. denied 11 January 1999, U.S. Lexis 493

²⁵³ Id.

²⁵⁴ Richard S. Shifreen, Molecular Diagnostics: The Challenge for the future, IVD Technology Magazine, Nov. Dec. 2000

²⁵⁵ Thomas R. Cech; Lorraine W. Egan; Carolyn Doyle; Elaine Gallin; Marshall A. Lichtman; Charles J. Quennan III; Nancy Sung. The Biomedical Research Bottleneck. (financial support for physician-scientists) , *Science*, July 27, 2001 v293 i5530 p573

budget of the NIH in the year 2002 was more than US\$ 27 billion. If it is linked to the US government spending on defense and space related research; there has been a continuous growth in government spending on research.

Q. 8. Is there any evidence for a “patent thicket” or tragedy of the anti-commons” problem in research and development? If so, what are the issues /effects?

A. Patent thicket or patent minefield where blockbuster is kept under perpetual monopoly through a series of subsidiary patents around the main patent has been discussed by Cohen and Suddards.²⁵⁶ Schondelmeyer²⁵⁷ has specifically mentioned the case of twenty-four subsidiary patents around the product “Tagamet.” The argument of Bendekgey and Hamlet Cox²⁵⁸ that patent thicket has not diminished aggregate research in biological research as a consequence of gene patenting is not based on any evidence except this bald assertion.²⁵⁹ Bendekgey is a counsel for Incyte, a firm having stake in patenting monopoly at the basic level of nucleotide and protein sequences. They have not even mentioned the number of patents filed. The number of patents filed is not an indication of rise in research. The patenting has flooded the USA because the patenting criteria has been consistently diluted during the period concerned notwithstanding the Guidelines related to Biotechnology issued in 1999. Practically each and every research is being patented. In fact, after one reads any article published in such journals, the first reaction is about number of patents that would have been claimed on the research. The flooding of patent has also been exacerbated because of defensive patenting.²⁶⁰ Wegner and Maebius discussed the tendency of defensive strategy by industries to avoid domination by other patents and to develop “a patent web that is interwoven throughout an area of technology that compels third parties to take a non-exclusive license.”²⁶¹ According to Wegner and Maebius, in coming two to three years, the USA

²⁵⁶ Lawrence J. Cohen and Hammond Suddards, *Limits on Enforcement of Intellectual Property Rights in International Licensing and Competition Law*, Susan Meek (ed) Center of international Legal Studies, Austria (1998)

²⁵⁷ Stephen W. Schondelmeyer, *Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures*, *Pharmaceutical Research in Management & Economics*, Prime Institute, College of Pharmacy, University of Minnesota (1999)

²⁵⁸ Lee Bendekgey and Dian Hamlet-Cox, *Gene Patents and Innovation* *Academic Medicine* vol. 77 (Dec. 2002) p. 1773

²⁵⁹ *Id.*

²⁶⁰ Harold C. Wegner & Stephen B. Maebius, *Patent Flooding: America’s New Patent Challenge*, Paper presented to the George Washington University Law School, April 22, 2002, *International and Comparative Patent Law*.

²⁶¹ *Id.*, p. 1

will have more than half a million applications per year.²⁶² Compared to the so called flooding of patents in the USA, Japan has reduced the number of patent filed through a number of measures including discouragement of the filing of utility model applications. Japan filed more than half million patent in 1987.²⁶³ Wegner went to the extent of calling them patent tax. In Japan, by mid 1980's, several of major electronic manufacturers filed thousands of patent applications per year. Mitsubishi Denki filed more than 20, 000 applications in one year alone. The patent tax through such patent thicket has yielded more than 1.7 billion US dollars to IBM in 2001²⁶⁴ and more than 1 billion dollars to Texas Instruments.²⁶⁵

Q. 9 Does biotechnology and genetic technology in particular, have special issues that warrant special treatment under patent law with respect to experimental use?

A. The experimental use exemption in every industry is required for scientific progress and increase in innovation. Biotechnological inventions got a lot more media coverage particularly because of their relationship with life saving drugs and ownership of the genes through a number of devises such as gene testing and rights over genetic information but the harm done to the scientific progress particularly in the context of Australian development of science and technology, the cost appears to be too high. The experimental use exemption should not distinguish between biological and non-biological technologies. It is meant for general scientific development and the technological progress and such progress should not be directed for one particular technology. Such act may also raise unnecessary controversy of discrimination in enjoyability of patent rights as per Article 27.1 of the TRIPS Agreement.

Q. 10 What is the justification for an experimental use exemption?

²⁶² A figure of 539,000 was projected for 2006. Setsuko Asami, A view toward the global Economy: Mutual Exploitation of Examination Results, AIPPI Journal (Japan), pp. 12-38, 15 (January 2002)

²⁶³ Japan Patent Office, Statistics, 1, <http://www.ipo.go.jp/> (2001)

²⁶⁴ Wegner & Maebius, supra note 260

²⁶⁵ Wineberg and Mantell, Managing Intellectual Property-An International Capital Asset, 99 Com. L. J. n. 2 (1994) (“Texas Instruments’ patent portfolio has become an independent profit center, contributing more than one billion dollars annually”)

A. The exceptional expansion in patenting through dilution of criteria of patenting has brought a flood of patenting monopoly in every field. Apart from patent thicket, and patent flooding,²⁶⁶ it has brought litigations in every nook and corner of innovations. A large number of patents are hidden and it is not possible for any body to know and understand such thicket and submarine patents. It is impossible for even the USPTO to examine the prior art forget others. In such circumstances, of dilution of patenting criteria along with total restriction on patentable subject matter would eliminate universities completely from any innovation and research activities. Unless, the universities and other research institutions are given certainty regarding litigations and the value of their research, the university research does not appear to be bright at all which countries like Australia at a particular level of developments would not be able to afford.

Q. 11. Is a criterion based upon whether the experimentation is on the invention itself as opposed to experimenting with an invention for its intended purpose (use) a useful criterion of determining “experimental use” in Australian patent law?

Ans. See below ans. for Q. 14

Q. 12 If so, is it sufficient by itself

Ans. See below ans. for Q. 14

Q. 13 Should an experimental use exemption cover only the situation where experimentation is the sole purpose of the use of the invention?

Ans. See below ans. for Q. 14

Q. 14 If not, what are alternatives or supplementary criteria for an experimental use exemption?

Ans. I am answering above four questions together. The four questions are pointing to the criteria adopted by the US Court of Appeals litigations concerning the experimental use exception to the curiosity and philosophical purposes in terms of contemporary meaning of philosophy and it should not pertain to the legitimate business of the infringer. The adoption of

²⁶⁶ Shapoiro, Patent Thickett ... NBER Working Paper NO. (2000)

such criteria would totally defeat the purpose of providing any exemption to the patent rights. The normal criteria adopted should be that any experimental use should not directly harm the commercial interest of the patent holder during the period of patents. This is the criteria normally adopted by the Japanese Supreme court²⁶⁷ and the German Supreme Court.²⁶⁸ The commerciality and non-commerciality of the experimental use is also to be eliminated as it is impossible to distinguish when an experiment would stay in its non-commercial character and when it would evolve into non-commercial use. New Zealand Court of Appeals made this observation in its decision where it accepted that submission of data would not infringe the patent but submission of the sample would. The fact that providing such flexibilities in the patent acts has not diminished scientific advancement of the German and Japanese patent acts would deal with the argument of the patent stake holder that it would diminish the bargain between the government and the inventor or diminish the economic value of the patent. The argument is the public purpose of the patenting monopoly and that public purpose is the advancement of science and technology and that should be the guiding factor.

Question 15. Are improved licensing practices by research organizations whole or partial alternatives to an experimental use exemption in Australia?

Ans. Improved licensing practices have not been able to solve the quest in of patent stacking, patent anti commons etc. The issue of licensing practices was discussed by Arti Rai and Eisenberg²⁶⁹ and Walsh et al.²⁷⁰ have discussed the issue of licensing and research. Walsh et al whose results are although based on interviews with the executives of the pharmaceutical and

²⁶⁷ The experimental use exception in the Japanese Patent Act 69(1) is limit reed only by art. 68 saying “ The Japanese Supreme Court articulated the limitation of the Japanese Experimental use exception by observing ““It is an act of infringement and impermissible, for a third party to manufacture generic drugs during the patent term to be assigned after the expiration of the patent or use [the drug beyond the extent that is necessary for experiments to be carried out in order to file under 14 of the Pharmaceutical Affairs Law.” (in Jennifer A Johnson, The Experimental Use Exception in Japan: A Model for U.S. Patent Law? 12 Pacific Rim L. & Pol’y 499, 518)

²⁶⁸ In *Klinische II*, the German Supreme Court discussed the limitation on experimental use privilege. It observed “Should the research have no relation whatsoever to technological theory or should the experiments be undertaken in such proportions as to no longer allow for justification on research grounds, then the activities are not considered to be permissible research activities within the meaning of Section 11 No. 2 of the Patent act. The same would be considered to be the cases if experiments are carried out with the purpose of persistently disturbing or hindering the inventor’s distribution of his product. In such cases, the research does not serve the purpose of technological progress, rather it serves as a means of the accomplishment of competitive purposes.” P. 436

²⁶⁹ Rai and Eisenberg, supra note

²⁷⁰ Walsh et al, 2002 supra note

biotechnological firms along with few from the offices of AUTM, the people interested in expansive role of patents, found a series of problems in technology transfer problems although they conclude that a “working solution ‘ is found. Such compromise solution even if it found would be a death bed of research in countries like Australia. Henry et al²⁷¹ observed that commercial firms had broad patenting strategy to develop portfolio that could be used to block other s from an area or to defend the firm’s ability to work in a particular field. The 1998 Report of the National Institute of Health Working Group of Research Tools identified a number of problems in accessing the patented research tools. Merz and his group as Pennsylvania University have also identified a number of issues for scientists to access patented research tools. The problem of access to research tools and research data is so acute that the pharmaceutical industry along with the Wellcome Trust, a U.K. consortium has sponsored a SNP (Single Nucleotide Polymorphisms)-identification effort with the explicit purpose of putting the information in the public domain. The main purpose is to avoid patents on SNPs.²⁷² Merck also tied to put to put information regarding expressed sequence tags (ESTs) into the public domain. Merck is also trying to create 150 patent free transgenic mice. Rai and Liebenberg concluded that “The willingness of private firms in a patent –sensitive industry to spend money to enhance the public domain is powerful evidence of a perception that intellectual property rights in the research results could create significant barriers to subsequent research and product development.” I have discussed some of the important examples of failure of licensing as promoting research page 33 of this note.

Q. 16. If, so, how could licensing practices be improved to provide a better outcomes for researchers?

Ans. There cannot be any such solution.

Q. 17 In what fields are patent pools a realistic whole or partial alternative to an experimental to an experimental use exemption in Australia?

A. Patent pool is not an answer to the well crafted legally certain experimental use exceptions. The historically famous patent pools in automobiles and aircraft emerged after lengthy litigations

²⁷¹ Henry et al, supra note

²⁷² SNP Consortium Website <http://snp.cshl.org/about>

and they have a tendency to behave anticompetitively. Arti Rai²⁷³ discussed the inapplicability of patent pool in biotechnological industry. The argument of formation of patent pool by market forces has been made in the USA. However, Rai and Eisenberg asserted that such development has not “been born out by the experience of the biomedical research community.”²⁷⁴ Wegner and Maebius gave examples from Henry Ford’s defensive patenting and Polaroid Camera inventors’ patent thicket, Polaroid could block any new comer.²⁷⁵ When Kodak challenged the patent monopoly of Polaroid, Polaroid alleged infringement of forty six claims of eleven patents. In fact, the firms having stake in patenting monopoly have favored to put such patents in public domain.²⁷⁶

Q. 18. Are the potential benefits of patent pools likely to outweigh their potential disadvantages?

A. As discussed above, patent pool cannot be an answer to experimental use exemption to instill a sense of certainty. The research community is the last community to get involved in any type of litigations.

Q. 19 Is compulsory licensing a realistic whole or partial alternative to an experimental use exemption in Australia?

A. Compulsory licensing is not an alternative to the well drafted experimental use exceptions. The compulsory licensing is covered by Article 31 of the TRIPS Agreement and it would have to follow the conditions prescribed in Article 31 of the TRIPS Agreement. These conditions are so impractical that none of developing countries who were most interested in such provisions was able to use the flexibility provided by presence of compulsory licensing in the TRIPS Agreement. The most important one is the payment of remuneration and the way it has been drafted, it can rarely go beyond litigations. Article 31(l) saying

‘(l) where such use is authorized to permit the exploitation of a patent (“second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

²⁷³ Arti Rai, Intellectual Property rights in Biotechnology: Addressing New Technology, 34 Wake Forest L. Rev. 827, 840 (1999), Arti Rai and Rebecca Eisenberg supra note

²⁷⁴ Arti Rebecca and Eisenberg, Bayh-Dole Reform and the Progress of Biomedicine, Law and Contemporary Problems, Winter/spring 2003 pp. 297-298

²⁷⁵ Wegner and Maebius, supra note

²⁷⁶ Arti Rai and Eisenberg, supra note 273

- (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- (ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and
- (iii) the use authorized in respect of the first patent shall be non-assignable except with assignment of the second patent.

Even without these additional conditions, the compulsory licensing has become a non-entity with practically no country being able to utilize it²⁷⁷ and with the onerous conditions prescribed in Article 31(l), it would be wastage of any amendment.

The compulsory licensing solution would be no solution at all for experimental use exceptions particularly when it is permitted under Article 30 of the TRIPS Agreement permitting greater flexibility and less litigation.

Q. 20 For this to happen, do Australia's compulsory licensing provisions need to be changed?

A. Above answer of limitations of compulsory licensing provides the answer to this question. Compulsory licensing can only invite litigations and that would amount to suffocating the innovations.

²⁷⁷ Amir Attaran, The Doha Declaration on the TRIPS Agreement and Public Health: Access to Pharmaceuticals and Options under WTO Law, 12 Fordham Intellectual Property, Media and Entertainment Law Journal 859 (2002)