

# EXPERIMENTAL USE IN THE UNITED STATES: What does it mean for Australian Biotechnology?

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## Introduction

In 2003 the Australian Federal Government directed the *Australian Council for Intellectual Property* (ACIP) to commence an Inquiry to investigate and report on whether there is a need for an express experimental use defence<sup>1</sup> in the *Patents Act, 1990*. This Inquiry is relevant to biotechnology because the Government recognises the possibility that “patent rights may be inhibiting research and development, particularly in biotechnology”.<sup>2</sup> However, it is possible that any recommended statutory exemption could have a more general application.

In February 2004, ACIP issued an issues paper and requested written submissions by April 30, 2004.<sup>3</sup> In June 2004 it interviewed some of those that had made submissions.<sup>4</sup> In December 2004, it issued a discussion paper in which it sought further written submissions by February 2005.<sup>5</sup> The Report has now been completed and is expected to be sent to the Parliamentary Secretary of the Minister Industry, Tourism and Resources and IP Australia in the coming weeks.<sup>6</sup> Details of the Report however, will remain confidential until it is tabled by the Minister in the Australian Federal Parliament.

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<sup>1</sup> An experimental use defence in general terms is a legal defence to an action for patent infringement. Examples are experiments conducted to see if the ‘invention’ works or those motivated for purer research purposes. However, whether such an exemption operates at common law in Australia is debateable. There does exist a very restricted form of statutory exemption in s.78, *Patents Act, 1990*, but this only applies to patents for pharmaceutical substances which have been extended beyond the usual twenty year period of monopoly.

<sup>2</sup> The terms of the Inquiry require ACIP “to examine whether *some types of patents are inhibiting research and development* in Australia and determine whether both Australian researchers and business would *benefit from introducing an experimental use exception provision* (or some other provision) into the Australian patent legislation. In examining this question, ACIP should consider whether an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development” See ACIP *Patents and Experimental Use* Issues Paper, February 2004, 1 paras 2 and 3. (Emphasis added)

<sup>3</sup> The author made a written submission dated April 28, 2004.

<sup>4</sup> The author was interviewed on June 16, 2004.

<sup>5</sup> The author made a second written submission dated February 24, 2005.

<sup>6</sup> Confirmed in private correspondence with the secretary of ACIP, Mrs. Kaye Collins.

## **Experimental Use in the United States**

### *At common law*

Under the common law of the United States “it could never have been the intention of the legislature to punish a man, who constructed [a patented invention] merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of [the patented invention] to produce its described effects”<sup>7</sup> and for “the making of a patented machine to be [an infringement], [there] must be ... an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification”.<sup>8</sup> The cases from which these two passages come, *Whittemore v. Cutter* and *Sawin v. Guild*, were decided in 1813 by Justice Story.

According to Justice Story, the making of a patented invention for the purposes of purer (i.e., non-commercial) research or to verify the scope of the claims to the patented invention when compared to disclosures in the specification were not infringing acts. The exemption was not broad in scope.

In 1935 a mining school that used a patented invention in an educational setting was held not to infringe because the use was not connected with an “intent to derive profits or [a] practical advantage”<sup>9</sup> The words “practical advantage” in this context were not associated with the activities of the school which clearly derived an indirect advantage in the use of the patented invention in its educational role. These words required the use of the patented invention in a field of endeavour for which it was contemplated, such as mining.

In 1944<sup>10</sup> and 1958<sup>11</sup> the exemption was held to apply to experiments conducted by commercial organisations so long as there was no evidence that revenue was earned directly through the sale of the patented inventions. In the later case the court held that “there is no evidence that the [patented invention] was used other than experimentally.”<sup>12</sup> Therefore, according to these authorities even though the experimentation was conducted by companies in a field of endeavour for which the patents contemplated, provided the actual inventions were not a direct source of revenue, there was no ‘practical advantage’ derived from the experimental use of the patented inventions.

However, not all U.S. courts were so content to partition experimental uses of the patented inventions from the field of endeavour for which they were contemplated. Some courts considered that a ‘practical advantage’ was derived if the result of the experimental use led to the production of a product

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<sup>7</sup> *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

<sup>8</sup> *Sawin v. Guild* 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

<sup>9</sup> *Ruth v. Stearns-Roger Manufacturing Co* 13 F. Supp. 697, 713 (D. Colo. 1935), rev'd, 87 F.2d 35 (10th Cir. 1936).

<sup>10</sup> *Dugan v. Lear Avia* 55 F. Supp. 223 (S.D.N.Y. 1944), aff'd, 156 F.2d 29 (2d Cir. 1946).

<sup>11</sup> *Chesterfield v. United States* 159 F. Supp. 371 (Ct. Cl. 1958).

<sup>12</sup> *Ibid*, 375.

that itself was a source of revenue.<sup>13</sup> Certainly, by the 1970's the attitude of the courts endorsed a more restricted form of exemption. For example, in *Pitcairn v United States*<sup>14</sup> test flights conducted by the U.S. Government to verify that helicopters which it had purchased flew satisfactorily were held to be infringements because these 'experimental uses' came within the field of endeavour for which the patent contemplated. In other words, there was a commercial nexus between the experimental use and the user's business interests within the field of endeavour contemplated by the patent.

This line of reasoning was followed by the Court of Appeals for the Federal Circuit (CAFC)<sup>15</sup> in *Roche Products, Inc. v. Bolar Pharmaceuticals Co*<sup>16</sup>. In this case, Bolar Pharmaceuticals was a generic drug manufacturer that had conducted experiments on a patented drug during the term of a patent owned by Roche. The experiments were conducted for the purposes of the Food & Drug Administration (FDA) in accordance with the *Food, Drug, and Cosmetic Act*. The FDA requires animal and human experiments before it will authorise the production, distribution and sale of drugs in the United States. Even though Bolar Pharmaceuticals had no intention of producing, distributing and selling the patented drug prior to the expiry of the patent, in the course of conducting the bio-equivalence experiments it imported and used the patented drug. Roche sued Bolar Pharmaceuticals for infringement. On appeal, the CAFC agreed with Roche because "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 purposes."<sup>17</sup>

Most recently, the CAFC in *Madey v. Duke University*<sup>18</sup> narrowed the exemption even further. In this instance, Duke University continued to permit the use of an electron laser which was housed in its physics laboratories after its relationship with Madey, a former academic scientist and inventor of the laser, had ended. Madey sued Duke University for infringement as he argued that such continued use was unauthorised and therefore an infringement. The laser was actually used by the North Carolina Central University (NCCU) for experiments it was conducting for the U.S. military under the terms of a grant. In defence, Duke University argued that the experimental use by NCCU was exempt and therefore it was not infringing any of Madey's patents. The CAFC disagreed and held,

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<sup>13</sup> *Pairpearl Prods., Inc. v. Joseph H. Meyer Bros.*, 58 F.2d 802, 804-05 (D. Me. 1932).

<sup>14</sup> *Pitcairn v. United States*, 188 U.S.P.Q. (BNA) 35 (Ct. Cl. Trial Div. 1975) (affirming and adopting the trial court's decision regarding the experimental use issue).

<sup>15</sup> The CAFC was established in 1982. Its role is to hear all appeals from US District Courts that concern patent law. Prior to the establishment of this specialised appellate court appeals from US District Courts were heard by a variety of appellate Federal Courts. The disparity in the rationale of patent appeal decisions that inevitably came from these federal Courts eventually led the U.S. Congress to establish the CAFC in an attempt to remove this disparity at appellate level.

<sup>16</sup> *Roche Products, Inc. v. Bolar Pharmaceuticals Co.*, 733 F.2d 858 (Fed. Cir. 1984).

<sup>17</sup> *Ibid*,

<sup>18</sup> *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.<sup>19</sup>

Until the U.S. Supreme Court rules specifically on the common law experimental use defence, the CAFC's ruling in *Madey v Duke University* remains law in the United States. What it means is that the exemption is very narrow indeed. Activities of universities and other teaching or research institutions will not automatically fall within its scope merely because of their status or primary function. It suggests that *any* 'practical advantage' derived by a user of a patented invention "in furtherance of [its] legitimate business", whether that be education or medical research, will be an infringement irrespective of whether that use lies within the field of endeavour contemplated by the patent or not.

One might say that the exemption is practically useless.

#### *Statutory exemption*

As a result of the CAFC decision in *Roche v Bolar Pharmaceuticals* the U.S. Congress amended the *Patents Act, 1952 (U.S.)* by inserting s.271(e)(1) which provides that it is not an infringement to:

. . . use . . . or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs.

Otherwise known as the *Drug Price Competition and Patent Term Restoration Act of 1984* or Hatch-Waxman Act, the U.S. Congress used this legislation to overturn *Roche v Bolar Pharmaceuticals*.

The implications of this law is clear. Experiments conducted for the purposes of FDA approval are exempt from patent infringement. Recently, however, the scope of that exemption was considered by both the CAFC<sup>20</sup> and the U.S. Supreme Court.<sup>21</sup>

The debate between the parties and the Courts revolved around the breadth of the words "reasonably related" in s.271(e)(1).

There were five U.S. Patents in issue. Each were owned by Integra Lifesciences and the Burnham Institute and they related to a tripeptide sequence 'Arg-Gly-Asp'. This tripeptide sequence promoted cell adhesion by attaching to three specific endothelial cell surface integrin receptors (the receptors). These patents were considered useful because "inducing better cell adhesion and growth should

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<sup>19</sup> *Ibid*, 1362.

<sup>20</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 2003.

<sup>21</sup> *Merck KGaA v. Integra Lifesciences I, Ltd.*, 2005 U.S. LEXIS 4840 (decision June 13, 2005)

promote wound healing and biocompatibility of prosthetic devices.”<sup>22</sup> This would also induce angiogenesis.<sup>23</sup>

Dr. Cheresch at the Scripps Research Institute (Scripps) had discovered in the course of research which had been funded by Merck KGaA (Merck) since 1988, that by blocking the receptors, angiogenesis would be inhibited. Dr. Cheresch went on to develop an onoclonal antibody (LM609) and a cyclic tripeptide (EMD 66203) to reverse tumour growth. These developments had obvious application in the treatment of some types of cancers and the objectives were opposite to “inducing better cell adhesion and growth”.

In July 1995, Dr. Cheresch, through Scripps, sought further funding from Merck. The funding application was for three years and its purpose was to develop “integrin antagonists as angiogenesis inhibitors”. The application contemplated both bench top and animal experiments (i.e., pre-clinical trials). It was anticipated that the results of these experiments would be used to seek FDA permission to conduct clinical (i.e., human) trials. This would involve the filing of an investigational new drug application (IND).<sup>24</sup> If the clinical human trials were successful then a new drug application (NDA) showing the new drug’s safety and efficacy in humans would be made for the purpose of enabling the marketing of that new drug.<sup>25</sup> Dr. Cheresch and Scripp’s funding application was accepted by Merck and it entered into an agreement with Dr. Cheresch and Scripps.

During 1996 Integra learnt of these experiments and invited Merck to enter into a license because the “angiogenesis research [being conducted by Dr. Cheresch and Scripps] was a commercial project that infringed [Integra’s tripeptide] related patents”.<sup>26</sup> Merck refused Integra’s invitation. Integra believed that its tripeptide patents were infringed despite the fact that Dr. Cheresch’s work was to be used to inhibit angiogenesis not to induce it. Furthermore, to the extent that Dr. Cheresch and Scripp’s used the patented inventions they were as research tools in the ‘hunt’ for a new anti-cancer drug.

Integra was unimpressed by these distinctions. It maintained that the patented tripeptide patents captured any use of the tripeptide in these circumstances. The CAFC agreed and held:

The Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds. The

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<sup>22</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 2003, I.

<sup>23</sup> “Angiogenesis is the process by which new blood vessels sprout from existing vessels; it plays a critical role in many diseases, including solid tumor cancers, diabetic retinopathy, and rheumatoid arthritis.” Per Scalia J, 7-8.

<sup>24</sup> Under the *Food, Drug, and Cosmetic Act* the FDA is required to decide whether “the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation” [s. 355(i)(3)(B)(i)] based upon “pharmacological and toxicological studies of the drug involving laboratory animals or in vitro” [s. 312.23(a)(8)].

<sup>25</sup> S. 355(b)(1). The NDA must include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties. [ s. 314.50(d)(2) (preclinical studies) and (d)(5) (clinical studies).]

<sup>26</sup> *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 2003, I.

FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval. For instance, the FDA does not require information about drugs other than the compound featured in an Investigational New Drug application. Thus, the Scripps work sponsored by Merck was not "solely for uses reasonably related" to clinical testing for FDA.<sup>27</sup>

The U.S. Supreme Court was subjected to many *amicus curiae* briefs. Interestingly, it was universities that argued for a narrow exemption<sup>28</sup> and pharmaceutical manufacturers for a broad exemption.<sup>29</sup> The U.S. Government also intervened by arguing for a broad exemption.<sup>30</sup>

Whether it was the treatment of cancer that encouraged the U.S. Government to intervene is mere speculation, but clearly the breadth of the exemption was paramount in the ability of Dr. Cheresch, Scripps and Merck to develop an anti-cancer drug and this was relevant to the U.S. Government and its ageing constituency.

Justice Scalia, the author of the unanimous opinion held that the distinction between pre-clinical and clinical data which the CAFC made was incorrect because "the FDA requires that applicants include in an IND summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals"<sup>31</sup> and pointed out that "the FDA does not evaluate the safety of proposed clinical experiments in a vacuum; rather, as the statute and regulations reflect, it asks whether the proposed clinical trial poses an 'unreasonable risk.'"<sup>32</sup>

He agreed however, that experiments "performed *without the intent* to develop a particular drug or a *reasonable belief* that the compound will cause the sort of physiological effect the researcher intends to induce"<sup>33</sup> will fall outside of the scope of the exemption, but even so, this does not mean that "experimentation on drugs that are not ultimately the subject of an FDA submission"<sup>34</sup> will fall outside of the exemption. It will depend on the circumstances.

In conclusion Justice Scalia held,

The use of a patented compound in experiments that are not themselves included in a 'submission of information' to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the 'development and submission of information' to the FDA does not become more attenuated

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<sup>27</sup> *Ibid*, II.A [15].

<sup>28</sup> See Brief Of Amici Curiae Wisconsin Alumni Research Foundation, The American Council On Education, Boston University, The Regents Of The University Of California, Research Corporation Technologies, The Salk Institute For Biological Studies, University Of Alberta And University Of Oklahoma In Support Of Respondents

<sup>29</sup> See Brief For The Pharmaceutical Research And Manufacturers Of America In Support Of Petitioner.

<sup>30</sup> See Brief For The United States As Amicus Curiae.

<sup>31</sup> Per Scalia J, [18].

<sup>32</sup> *Ibid*, [19].

<sup>33</sup> *Ibid*, [23] (Emphasis added).

(or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA.<sup>35</sup>

It would seem therefore that provided that the experiments are designed and performed with a reasonably held intent to seek FDA approval, that even if that approval is not ultimately sought and even if the results of those experiments are not included in an application for FDA approval, that there is no patent infringement.

Clearly, the statutory exemption is much broader than the exemption at common law. Whether this disparity will be maintained by the U.S. Supreme Court when it is ultimately positioned to make this determination is unclear. The fact that the U.S. Congress has specifically limited the statutory exemption to a specific application suggests that it did not intend to broaden that exemption to other types of inventions, however, the U.S. Supreme Court's critique of the CAFC's narrow interpretation of the statutory exemption in *Merck v Integra* suggests that it may seek to broaden the common law exemption. After all, the CAFC's decision in *Madey v Duke University* has rendered it practically useless as a defence and it is unlikely that Justice Story intended this when he first formulated it in 1813.

### **Impact on Australian Biotechnology Companies.**

Given that for many Australian biotechnology companies penetrating the U.S. market remains a high priority, their ability to avail themselves of the statutory exemption is important, especially when FDA approval is essential to the marketing of any drug in that market. Irrespective of whether the drug is (a) about to come out of U.S. patent protection or (b) is for a new drug, the s.271(e)(1) exemption is useful to Australian biotechnology for the following reasons:

Firstly, there is no Australian court authority regarding the *Patents Act, 1990* regarding the application of a common law experimental use exemption as a defence to patent infringement. Therefore, to undertake experiments in Australia using patented genetic sequences as research tools is problematic even for an educational or research based organisation, and even if such use is for 'purer' research. Such use could well come within the definition of 'exploit' contained in the Australian legislation.<sup>36</sup>

Secondly, as there is no statutory provision in the *Patents Act, 1990* equivalent to s.271(e)(1), even if a common law exemption was held to apply in Australia, use of patented research tools in Australia in experiments designed with a commercial objective or which provide the users with a practical benefit

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<sup>34</sup> *Ibid.*

<sup>35</sup> *Ibid.*, [25].

<sup>36</sup> For a full explanation see the submission of L. Palombi to ACIP dated February 24, 2005.

may fall outside such an exemption. This is especially so if Australian courts follow the trend set by the CAFC in *Roche v Bolar Pharmaceuticals* and *Madey v Duke University*.

Thirdly, many patents that have been applied for or granted in the U.S. have corresponding filings and grants in Australia, so that generally patented research tools in the U.S. are also patented in Australia.

Finally, it is possible for Australian biotechnology companies to design and conduct experiments directly or indirectly in the U.S. with the intention of seeking FDA approval, thereby obtaining the benefit of the broad statutory exemption for those experiments in the U.S. Once FDA approval is obtained seeking regulatory approval in Australia or the EU may be facilitated more rapidly.

It is important to appreciate that today there are thousands of patents over isolated genetic sequences that are or have the potential for use as research tools. While such use continues to be problematic in Australia, the guidance of the U.S. Supreme Court in *Merck v Integra* provides Australian companies that have the U.S. market in their sites with instruction as to how to freely use U.S. patented inventions in the 'hunt' for new drugs. Provided that there is an intention to conduct those experiments with a view to seeking FDA approval and that the conduct is reasonably designed to achieve that objective, then irrespective of whether that objective is ultimately reached, such use cannot be the subject of a patent infringement suit in the U.S.

#### **ACIP and Experimental Use.**

With the ACIP Report only a few weeks away from being sent to the Parliamentary Secretary of the Minister Industry, Tourism and Resources and IP Australia, there is no point speculating on what it will recommend for Australia. We will all know soon enough. One can only hope that ACIP recommends protection that is as broad as that provided by s.271(e)(1) and as interpreted by the U.S. Supreme Court. This is particularly important in view of the US and Australian Free Trade Agreement which seeks to put Australian and U.S. business interests on a level playing field.

It may be that broad patent infringement exemptions appear to undermine the argument that strong patent laws are good for industry, but given the lead from the U.S., a stalwart in free enterprise and intellectual property protection, for the Australian Government to take a divergent path means that it runs the risk of being parochial and enticing medical and scientific research away from Australia and to the United States.