

# Depositing Seeds to Comply with the *Patents Act 1990* (Cth) – The Adequacy of Definition and Description?

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## Introduction

Patents are generally considered to be a utilitarian scheme to promote invention and address the market failure for invention.<sup>1</sup> According to this model, effective competition together with good market information may create a disincentive to markets inventing (the market failure) because new developments may be rapidly copied without the recovery of the inventor's development costs (a free ride).<sup>2</sup> A patent under the *Patents Act 1990* (Cth) theoretically compensates for this market failure and facilitates a limited period of exclusive rights during which the inventor may exclude others in order to recover the development costs (confounding the free riders) and contribute to beneficial invention (and enhanced competition for the welfare of consumers) by investing in new developments.<sup>3</sup> The consequence of a patent privilege is in effect a

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- <sup>1</sup> There may be a distinction between the terms 'invention' and 'innovation', the term 'invention' being a step in the first steps in the process of 'innovation'. In this distinction, 'innovation' would include all the commercial requirements to place an 'invention' on the market, including product development, marketing, and so on. This distinction is important as patents are an incentive to 'invention', but it is *not* clear whether they should also be an incentive to 'innovation'. In effect, this distinction reflects the differences between the 'reward' and 'prospect' theories justifying patent privileges: see for example Kevin Rhodes, 'The Federal Circuit's Patent Non-obviousness Standard: Theoretical Perspectives on Recent Doctrinal Changes' (1991) 85 *New York University Law Review* 1051, 1076-1100.
- <sup>2</sup> Commonwealth, Australian Competition and Consumer Commission, *Application of the Trade Practices Act to Intellectual Property* (1991), 8; see generally Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 134-178.
- <sup>3</sup> Australian Competition and Consumer Commission, above n 2, 8; for a review of the policy objectives of patenting see Thomas McCarthy, 'Intellectual Property and Trade

prohibition on use (a franchise) and re-invention of the invention disclosed in the patent specification.<sup>4</sup> This franchise is the incentive that theoretically promotes new and useful inventions that in the long term promote more effective competition (presumably for the benefit of consumers).<sup>5</sup>

Central to the justification for a patent franchise is an adequate disclosure in the complete specification,<sup>6</sup> both defining the scope of the invention<sup>7</sup> so that competitors can avoid infringement,<sup>8</sup> and describing its nature and operation, so that it might be performed after the term has expired.<sup>9</sup> This is achieved by the *Patents Act 1990* (Cth) which requires, as a threshold, that a complete specification<sup>10</sup> define the scope of the invention with clear

Practices Policy: Coexistence or Conflict? The American Experience' (1985) 13 *Australian Business Law Review* 198, 200-203; note that there are different theoretical views about whether disclosure is a primary purpose of patenting, or merely an additional benefit: see for example United States of America, Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), ch 1 (6).

- <sup>4</sup> For an analysis of this proposition see Martin Aldeman, 'Property Rights Theory and Patent-Antitrust: The Role of Compulsory Licensing' (1977) 52 *New York University Law Review* 289, 292-299.
- <sup>5</sup> Noting that the intention of the *Patents Act 1990* (Cth) was to 'modify the Australian patent laws, adjusting the length, strength and breadth of patent rights so as to maximise the social benefits and minimise the social costs to Australians' Commonwealth, *Parliamentary Debates*, House of Representatives, 1 June 1989, 3479 (Minister for Science) noting the incorporation of this speech into the Patents Bill Second Reading Speech at Commonwealth, *Parliamentary Debates*, Senate, 29 May 1990, 1271.
- <sup>6</sup> A 'complete specification', in contrast to a 'provisional specification', means 'a specification filed in respect of a complete patent application or, if the specification has been amended, the complete specification as amended': *Patents Act 1990* (Cth) sch 1; noting that '[t]he Commissioner or a court may, in interpreting a complete specification as amended, refer to the specification without amendment': *Patents Act 1990* (Cth) s 116; the development of 'specifications' in patent law reflects the requirement for distinct description and claiming requirements: *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123, 128 (McTiernan J); see also *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481, 497-499 (Spender, Gummow and Heerey JJ).
- <sup>7</sup> The term 'invention' in the context of the *Patents Act 1990* (Cth) s 40(2) means 'the embodiment which is described, and around which the claims are drawn': *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 15 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).
- <sup>8</sup> See *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123, 128 (McTiernan J).
- <sup>9</sup> See *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 16 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ) citing *No-Fume Ltd v Frank Pitchford & Co Ltd* (1935) 52 RPC 231, 243 (Romer LJ).
- <sup>10</sup> Noting that different requirements apply to a 'provisional specification': *Patents Act 1990* (Cth) s 40(1) where some generality and uncertainty in describing the general nature of the invention is probably acceptable: see *Speedy Gantry Hire Pty Ltd v Preston Erection Pty Ltd* (1998) 40 IPR 543, 562 (Emmett J).

and succinct claims<sup>11</sup> and also describe the invention fully, including the best method known to the applicant for performing the invention.<sup>12</sup> The defining and describing requirements of the *Patents Act 1990* (Cth) also have important consequences for ensuring that undisclosed information about the invention does not enjoy the benefits of a statutory monopoly,<sup>13</sup> that disclosing information may benefit competitors seeking to substitute or imitate the patented invention during its term (and using the invention at the end of its term) promoting greater competition and benefits for consumers,<sup>14</sup> and maintaining the integrity of the registration scheme so that the application can be distinguished from the prior art and as a benchmark against future claims of infringement.<sup>15</sup>

This article sets out to examine the problems associated with the deposit of seeds with a depositary authority to adequately define and describe a seed or plant invention under the *Patents Act 1990* (Cth).<sup>16</sup> The problem, it is argued, is that sexually produced seeds are heterogeneous biological materials and so a seed deposit is a representative sample of the invention, with only some of the seeds likely to be the invention and there being no certainty that any of the seeds are the best example of the invention (see Box 1). The consequence of this problem, it is argued, is that depositing sexually produced seeds may fail to satisfy the *Patents Act 1990* (Cth) definition and description requirements. To illustrate these concerns the article examines a particular patent's complete specification and then assesses the construction of that specification to illustrate why IP Australia<sup>17</sup> and courts should carefully consider such claims in applying the threshold requirements of the *Patents Act 1990* (Cth).

<sup>11</sup> *Patents Act 1990* (Cth), ss 40(2)(b) and 40(3); this is a requirement of examination (*Patents Act 1990* (Cth), s 45(1)(a)), and also a ground for opposition (*Patents Act 1990* (Cth), s 59(c)) and revocation (*Patents Act 1990* (Cth), s 138(3)(f)).

<sup>12</sup> *Patents Act 1990* (Cth), s 40(2)(a); this is a requirement of examination (*Patents Act 1990* (Cth), s 45(1)(a)), and also a ground for opposition (*Patents Act 1990* (Cth), s 59(c)) and revocation (*Patents Act 1990* (Cth), s 138(3)(f)).

<sup>13</sup> See for example *American Cyanamide Co v Ethicon Ltd* (1979) RPC 215, at 269 (Graham J).

<sup>14</sup> For an elegant statement of these policy objectives see *Proctor & Gamble Inc v Unilever Plc* (1995) 33 IPR 627, at 637 (Stone JA).

<sup>15</sup> See Charles Lawson, "Sufficiency" for living organism inventions under the *Patents Act 1990* (Cth) (2004) 11 *Journal of Law and Medicine* 373, at 374.

<sup>16</sup> For a review of the patentability of seed and plant inventions see IP Australia, *Australian Patents for Plants* (2002).

<sup>17</sup> IP Australia is the IP Australia is the federal government agency responsible for granting rights in patents, trade marks and designs. For more information see the IP Australia website at <<http://www.ipaustralia.gov.au>>.

The selected Australian patent application in this article, titled *New Pepper Variety*,<sup>18</sup> both defines and describes the plant invention by reference to a seed deposit. While this application has been abandoned in Australia, a patent was granted in the United States for a specification and claims in identical terms.<sup>19</sup> The next part of the article reviews the complete specifications setting out the nature of the invention as background to an analysis of the way a court might be expected to construe the claim. The following part sets out the particular problems raised by defining and describing a plant invention by reference to a seed deposit. The next part considers the laws about claim clarity and succinctness that define the invention. The next part considers the laws that apply to the adequacy of describing such a plant invention by reference to its deposited seeds. The following part examines recent decisions from the United States that might provide some clarity to the issues about adequately defining and describing a deposited invention. This article will conclude that defining and describing a heterogeneous seed deposit needs to be carefully considered to ensure the objectives of the *Patents Act* are being achieved.

## The Plant Invention

The plant invention considered in this article<sup>20</sup> was claimed as follows:

1. A hybrid pepper plant grown from seed deposited with the ATCC<sup>21</sup> under Accession No PTA-2275.

<sup>18</sup> Australian Standard Patent Application 200143267, *New Pepper Variety*, Allan Nash (2001).

<sup>19</sup> United States Patent 6,498,287, *New Pepper Variety*, Allan Nash (2002); the only significance placed on the United States Patent and Trademark Office granting this application is that it illustrates the need for caution in assessing these kinds of applications and that some of the issues raised in this article are real and might need to be taken into account in Australia.

<sup>20</sup> The quoting of the extracts of the complete specification has maintained exactly the same characters with no changes to amend typographical errors or other style choices. Notably, a complete specification is a public document directed to a person skilled in the relevant art and the characters (or illustrations) may disclose meaning to such a person (see for example *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 242-243 (Diplock LJ)), although it is the meaning of the words and other illustrations that is significant and not the information a person skilled in the relevant art would derive from the words or illustrations: see *British Celanese v Courtaulds Ltd* (1935) 52 RPC 171, 196 (Tomlin LJ).

<sup>21</sup> The American Type Culture Collection (ATCC) accepts plant tissue cultures (twenty five frozen samples of callus tissue) although the ATCC prefers seeds (2500 seeds in 100 labelled packets of 25 seeds each; although the ATCC will accept less where there is justification (but not less than 625); see also American Type Culture Collection, *Budapest Treaty Deposit Form BP/1* (2003).

2. Fruit harvested from the plant of claim 1.
3. Hybrid seed which can be grown to yield a pepper plant of claim 1.<sup>22</sup>

This claim was 'directed to a new pepper variety that bear fruit that are sweet, red and low-seeded and resemble a Jalapeno pepper in size and shape' and 'a method for making the plants [is] also provided'.<sup>23</sup> The invention was summarised as:

The present invention provides sweet, low-seeded hybrid peppers that resemble a Jalapeno pepper in size and shape. When fully mature, the fruit are red in color, 11/4'-23/4' in length and 3/4-11/2' in diameter. Brix.degree. measurements are greater than 9.0. Usually, the plants of the invention result from crossing a first inbred pepper plant having low-seeded, Jalapeno-shaped red fruit by a second inbred pepper plant having low-seeded Jalapeno-shaped orange fruit.

In this invention, a sweet, red, low-seeded pepper hybrid is produced. An exemplary line is DNAP 98004 (Pepper seed (*Capsicum annum*) 98004 deposited under the terms of the Budapest Treaty on Jul. 28, 2000 as ATCC Accession No. PTA-2275 with the American Type Culture Collection in Manassas, Va.). The parental lines are DNAP 89300 (PVP 8800202, Vegi-Sweet), as the female parent and DNAP 94166 as the male parent. The invention also provides pepper fruit and seed produced by such hybrids. In addition, the invention provides pepper seed that can be grown to yield a hybrid plant of the invention.

The invention further provides methods of making a hybrid pepper that is sweet, red, and low-seeded and resembles a Jalapeno pepper in size and shape. The methods comprise crossing a first red-fruited pepper plant that is sweet, low-seeded and resembles a Jalapeno pepper in size and shape with a second orange, fruited pepper plant that is sweet, low-seeded and resembles a Jalapeno pepper in size and shape. F1 plants that are red-fruited, sweet, low-seeded and resemble a Jalapeno pepper in fruit size and shape are then selected.

Both parental lines are produced by crossing and pedigree selection to identify progeny having the desired traits. In particular, both parents

<sup>22</sup> New Pepper Variety, above n 18; other similar Australian patents claiming plants and depositing seeds with a depositary authority includes, for example, Australian Standard Patent 769754, *Herbicide Tolerant Brassica Juncea and Method of Production*, Gregory Gingera *et al* (2001); Australian Standard Patent Application 199853678, *Inbred Corn Line qh101*, John Geadlemann and Kenneth Leto (1998); Australian Standard Patent Application 199346884, *Improved Inbred Corn Lines*, The Upjohn Company (1993).

<sup>23</sup> New Pepper Variety, above n 18, Abstract.

should produce fruit that are sweet, low-seeded, and resemble a Jalapeno pepper in size and shape. Preferred lines for this purpose are DNAP 89300 and DNAP 94166.<sup>24</sup>

The specification defines the following terms:

...a first plant 'grown from' seed of a second plant includes one that arises directly or indirectly from the seed of the second plant. Thus, the first plant may be an F.sub.1 or more removed generation produced by standard breeding techniques using the second plant as parent, so long as the first plant has all the characteristics of the second plant. A first plant has 'all the characteristics of' a second plant if it shares all the relevant morphological and physiological characteristics of the second plant. For example, in the case of the pepper plants of the invention, the main distinguishing characteristics of the plant are fruit color, sugar content, seed number, and shape, as described here.

'Brix.degree.' is used as a measure of sugar content of the fruit of the invention. Brix.degree. is a standard refractometric measure of sugars. One Brix.degree. unit is approximately 1% sugar by weight. As used here a 'sweet' pepper fruit is one having a Brix.degree. reading of at least 8.0, preferably about 9.0.

A pepper fruit that is 'Jalapeno pepper in size and shape' is one that has as a generally long, cylindrical shape. Typically, the fruit are between about 1 and about 3 inches in length. The fruit are usually between about 0.5 inches and about 2 inches in diameter.

A 'low seeded' fruit is one that comprises less than about 30 seeds.<sup>25</sup>

The specific embodiments of the invention are described as:

The hybrid plants of the invention result from a cross of parental lines that bear fruit that are sweet, low-seeded, and resemble a Jalapeno pepper in fruit size and shape. Preferred lines for this purpose are DNAP 89300 and DNAP 94166. DNAP 89300 (PVP 8800202) has been identified in the segregating populations of a cross between Sweet Bell (PVP 8700124) and P.I. 379183. DNAP 94166 has been identified in the segregating populations of a cross between Corona and DNAP 89382 (a sister selection to DNAP 89300). The F1 generation is then examined for the presence of red fruit that are sweet, low-seeded and resembling a Jalapeno pepper in fruit size and shape. Sweetness is measured in the laboratory by measuring Brix.degree. levels. Low-seeded refers to approximately less than or equal to 30 seed per fruit. The red color is caused by alleles that are dominant.

These hybrids of the invention have a compact semi-erect habit, with intermediate branching. Leaves are elliptic and medium-large in size.

<sup>24</sup> Ibid Summary of the Invention.

<sup>25</sup> Ibid Definitions.

Foliage is a medium-green color. There is one flower per leaf axil. The corolla is white and the style is slightly shorter than the stamens in length. Fruit are smooth, pendant, and slightly blunt at the apex. Fruit have 1-2 locules and oblong in shape. The pedicel is medium in length and straight to slightly curved. Seed are yellow and there are less than 30 per fruit.

The above examples are provided to illustrate the invention but not to limit its scope. Other variants of the invention will be readily apparent to one of ordinary skill in the art and are encompassed by the appended claims. All publications, patents, and patent applications cited herein are hereby incorporated by reference for all purposes.<sup>26</sup>

The next part identifies the problems raised by this specification and claims of a plant invention relying on a deposit of the seeds to adequately define and describe the invention.

### The Problem

In approaching questions about the meaning of a patent specification, courts generally examine the specification to determine what has been invented and claimed, and then proceed to consider the various objections to the validity of particular claims.<sup>27</sup> The exercise of construing the claims and specification is crucial, as the patent privileges are limited to what has actually been claimed.<sup>28</sup> The *New Pepper Variety* specification identifies both a new plant as a product and a process for making those plants.<sup>29</sup> The invention itself appears to be a 'new' pepper variety that is characterised by having 'red fruit that are sweet, low-seeded and resembling a Jalapeno pepper in fruit size and shape'.<sup>30</sup> As a generalisation, the evident invention from a reading of the complete specification involves a plant (and seeds) with specific characteristics when cultivated, although the claims do not expressly identify those characteristics. The specification sets out sexual crosses of female and male plants exhibiting desirable characteristics and then selection of progeny plants that have particular desirable characters.<sup>31</sup> It is asserted

<sup>26</sup> Ibid Description of the Specific Embodiments.

<sup>27</sup> See *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 609 (Dixon CJ, Kitto and Windeyer JJ); *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 12 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ); notably it is not legitimate to construe the claim according to the alleged infringement: *Ransburg Company v Aerostyle Ltd* (1968) RPC 287, 297 (Upjohn LJ).

<sup>28</sup> See *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ).

<sup>29</sup> New Pepper Variety, above n 18, Summary.

<sup>30</sup> Ibid Description of the Specific Embodiments.

<sup>31</sup> Ibid Summary.

that the specification is illustrative of the invention and that the claims capture other variants of the invention.<sup>32</sup>

Adopting a conservative construction approach which focuses only on the words of the claims without reference to the specification, arguably the claims are ambiguous. Applying a plain, ordinary meaning to the claims<sup>33</sup> suggests that the meaning and scope of the patent privilege in this matter is ‘hybrid pepper plants’ and their fruits grown from the deposited seeds (claims 1 and 2) and any seeds that can be grown to ‘yield’ those plants (claim 3). Claims 1 and 2 appear to be confined to the plants and fruits grown from the deposited seeds, while claim 3 appears on its face to extend more broadly to *any* ‘hybrid seeds’ that can ‘yield’ the ‘pepper plants’ that can be grown from the deposited seeds. The ambiguity arises here, as it is not clear which characters the deposited seeds have that ‘hybrid seeds’ could be grown to ‘yield’. That is, it is uncertain whether the invention is confined only to the deposited seeds, or relates to a broader invention of which the deposited seeds are a representative sample, and if so, the characters of the plant grown from the deposited seeds that the ‘hybrid seed’ must possess. This in turn arguably casts doubt on what exactly has been claimed by depositing the seeds referred to in claims 1 and 2 as, on the face of the claims, it is unclear what the invention is that is exhibited by the deposited seeds. To resolve this uncertainty the specification must be consulted and the terms of the claim understood in the context of the specification.

However, courts generally directly consider the construction of claims in the context of the whole specification, and not after an ambiguity has been identified in the claims, so that understanding the use of the words in the claim in the context of the complete specification can render ambiguity in the claims.<sup>34</sup> If the context of the complete specification is taken into account, then the meaning and scope of the claims to a ‘hybrid pepper plant’ and ‘fruit’ grown from the deposited seed suggests that the invention in the plants grown from the deposited seeds will have the

<sup>32</sup> Ibid Description of the Specific Embodiments.

<sup>33</sup> See *Welch Perrin & Co Pty Ltd v Worrel* 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ).

<sup>34</sup> Thus Justice Hely in *Flexible Steel Lacing Co v Beltreco Ltd* (2000) 49 IPR 331, 347-348 appears to accept Justice Sheppard’s consideration in *Decor Corp Pty Ltd v Dart Industries Inc* (1988) 13 IPR 385, 410-411 that the modern approach to determining the meaning and scope of claims was to read the whole specification to understand the meaning of the words of the claim in the context in which they were used was appropriate, and that this approach was supported by the earlier practice as illustrated by Justice Aickin in *Minnesota Mining & Manufacturing Co v Beiersdorf (Aust) Ltd* (1980) 144 CLR 253, 267-272.

characters of being 'sweet, red and low-seeded and resemble a Jalapeno pepper in size and shape',<sup>35</sup> as some of those terms are defined in the complete specification.<sup>36</sup> The specification also discloses that the deposited seeds that are the invention (DNAP 98004) for the purposes of claim 1 are the progeny (being an 'exemplary line')<sup>37</sup> of crossing the parental lines DNAP 89300 (a red-fruited plant) as the female parent and DNAP 94166 (an orange-fruited plant) as the male parent,<sup>38</sup> presumably being a suitably characterised 'inbred pepper plant having low-seeded, Jalapeno-shaped red fruit' with an 'inbred pepper plant having low-seeded Jalapeno-shaped orange fruit' respectively.<sup>39</sup> According to the specification these preferred parental lines are themselves the result of segregating populations.<sup>40</sup> The progeny are then selected for the segregating red-fruited dominant alleles and then the other segregating characters of sweet, low-seeded and resembling a Jalapeno pepper in size and shape.<sup>41</sup> Thus, the deposited seeds are a population of sexually crossed parental varieties exhibiting the range of possible segregating characters, some of which may include some or all of the characters of fruit that is red, sweet, low-seeded and resembling a Jalapeno pepper in size and shape, although these characters will be in a range of genetic backgrounds. The ambiguity arises in determining what exactly has been invented that is exhibited by the deposited seeds and exactly how broadly these claims apply to other pepper plants and seeds.

From each approach to construing the claims, the ambiguity arises from the perspective that each deposited seed has a unique genetic composition that is essentially different to its parents<sup>42</sup> and different to the other progeny.<sup>43</sup> Thus, the problem this application illustrates is that sexually produced seeds are heterogeneous biological materials and so a seed

<sup>35</sup> New Pepper Variety, above n18, Summary.

<sup>36</sup> *Ibid* Definitions.

<sup>37</sup> *Ibid* Summary.

<sup>38</sup> *Ibid*.

<sup>39</sup> *Ibid*.

<sup>40</sup> *Ibid* Description of the Specific Embodiments.

<sup>41</sup> *Ibid*.

<sup>42</sup> Notably, apomictic (of apomixic) seeds produced asexually, that is, independently of fertilisation (the fusion of female and male gametes), may in some circumstances, be genetically identical to their parent, although pepper (genus *Capsicum*) does not generally exhibit this characteristic.

<sup>43</sup> It is theoretically possible for two independently sexually reproduced offspring to be identical, but practically unlikely given the re-assortment of nucleic acids (prophase 1) and random distribution of chromatids (metaphase 1) during meiosis. Thus, the random distribution of chromatids for humans ( $n=23$ ) is  $2^{23}$  possible outcomes. The distribution for rearranged chromatids and nucleic acids will be significantly greater than this.

deposit is, in effect, a representative sample of the invention, with only some of the seeds likely to be the invention and there being no certainty that any of the seeds are necessarily the best example of the invention. This goes to the primary objectives of the defining and describing requirements in the *Patents Act 1990* (Cth). The following parts consider the standards required by the *Patents Act 1990* (Cth) to adequately define and describe such an invention.

### **An Adequate Definition – ss 40(2)(b) and (3)**

The *Patents Act 1990* (Cth) requires that the ‘claim or claims defining the invention’<sup>44</sup> be ‘clear and succinct’.<sup>45</sup> The intention of this provision is that the claims must unambiguously define the boundary of the invention<sup>46</sup> for the benefit of competitors:

The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundaries of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed.<sup>47</sup>

Significantly, the certainty of meaning of the words used in the claims must achieve a higher standard than the words in the specification,<sup>48</sup> as a patent is ‘a public instrument which must, if it is to be valid, define a monopoly in such a way that it is not reasonably capable of being misunderstood’.<sup>49</sup> However, the boundaries of claims may tolerate some ambiguity where they do not affect questions of infringement.<sup>50</sup> Otherwise the general rules of construction apply requiring a ‘purposive’ approach, taking into account the knowledge of a person skilled in the art,<sup>51</sup> to determine the meaning and scope of the claims.<sup>52</sup> Importantly, the

<sup>44</sup> *Patents Act 1990* (Cth) s 40(2)(b).

<sup>45</sup> *Patents Act 1990* (Cth) s 40(3).

<sup>46</sup> See for example *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ).

<sup>47</sup> *Electric & Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39 (Lord Russell LJ).

<sup>48</sup> *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123, 130 (McTiernan J).

<sup>49</sup> *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ); see also *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ).

<sup>50</sup> See *Glaverbel SA v British Coal Corp* [1994] RPC 443, 495 (Mummery J).

<sup>51</sup> *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 242-243 (Diplock LJ); *Kirin-Amgen Inc v Hoechst Marion Roussel Inc* [2004] UKHL 46, [33] (Hoffmann LJ); see also *Flexible Steel Lacing Company v Beltreco Ltd* (2000) 49 IPR 331, 349 (Hely J); although noting the concern that ‘the court should act with some care before it broadens a claim in reliance upon a purposive construction of the words used in the specification’: *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* (2000) 49 IPR 225, 236 (Finkelstein J).

plain and unambiguous meaning of the claim cannot be varied or qualified by reference to the body of the specification,<sup>53</sup> although it is the specification as a whole that must be taken in context to determine whether the claims are clear and unambiguous.<sup>54</sup> Where there is some ambiguity in the claims the body of the specification may assist in clarifying the ambiguity or uncertainty,<sup>55</sup> although not in order to add 'glosses'<sup>56</sup> or to 'restrict, expand or qualify'<sup>57</sup> what is actually claimed.<sup>58</sup> Once the claims have been construed, the claim will only be invalid if it is so ambiguous that its 'proper construction' will always be in doubt.<sup>59</sup> That is, whether the claim unambiguously defines the scope of the patent privilege.<sup>60</sup> Further, the substance of an invention (being all its essential features and integers)<sup>61</sup> outside the express words of a claim will also be captured,<sup>62</sup> unless the wording of the claims clearly and deliberately leaves the thing outside the claim.<sup>63</sup>

- <sup>52</sup> Various judgements have set out summaries of the relevant rules of construction: see for example *Flexible Steel Lacing Company v Beltreco Ltd* (2000) 49 IPR 331, 347-350 (Hely J).
- <sup>53</sup> *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ); see also *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461, 478 (Barwick CJ and Mason J).
- <sup>54</sup> See the approach adopted in *Minnesota Mining & Manufacturing Co v Beiersdorf (Aust) Ltd* (1980) 144 CLR 253, 267-272 (Aickin J); see also *Decor Corp Pty Ltd v Dart Industries Inc* (1988) 13 IPR 385, 410-411 (Sheppard J); *Flexible Steel Lacing Company v Beltreco Ltd* (2000) 49 IPR 331, 347-348 (Hely J).
- <sup>55</sup> See *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ).
- <sup>56</sup> *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ).
- <sup>57</sup> *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461, 466 (Stephen J); see also *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ).
- <sup>58</sup> *Welch Perrin & Co Pty Ltd v Worrel* (1961) 106 CLR 588, 610 (Dixon CJ, Kitto and Windeyer JJ); *Interlego AG v Toltoys Pty Ltd* (1973) 130 CLR 461, 478 (Barwick CJ and Mason J), 466 (Stephen J).
- <sup>59</sup> *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ).
- <sup>60</sup> See *Flexible Steel Co v Beltreco Ltd* (2000) 49 IPR 331, 349 (Hely J); noting the additional rules of construction attempting to rationalise the various decisions about claim construction, 349-350.
- <sup>61</sup> *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 14 ALR 149, 157 (Gibbs J).
- <sup>62</sup> *Minnesota Mining & Manufacturing Co v Beiersdorf (Aust) Ltd* (1980) 144 CLR 253, 52-53 (Aickin J).
- <sup>63</sup> *Olin Corporation v Super Cartridge Co Pty Ltd* (1977) 14 ALR 149, 157 (Gibbs J).

Applying these standards IP Australia has accepted seed deposits as a clear and succinct definition of a plant invention.<sup>64</sup> However, if a court were to apply these standards to the *New Pepper Variety* application, it is arguable that the claims would be found to be ambiguous. Identifying the boundaries of what is claimed by depositing sexually produced seeds will always remain ambiguous because it is practically impossible to adequately define a heterogeneous biological material in a way such that ‘others may know the exact boundaries of the area within which they will be trespassers’.<sup>65</sup> Unfortunately, Australian courts have not been required to adjudicate such a matter to date. Perhaps a court might be concerned that the failure to adequately define a plant invention, in claims similar to the *New Pepper Variety* application, is particularly a problem where a competitor might seek to use the same parental varieties (being potentially elite germplasm varieties) to ‘invent’ a progeny line with different desirable characters to those of the segregating red, sweet, low-seeded fruit resembling a Jalapeno pepper in size and shape, and wants to distinguish their independent invention. Without a clear definition of the invention, a competitor will remain uncertain about infringement and potentially avoid making use of the parental varieties to make such an invention so as to avoid possible infringement because some of the segregating progeny may repeat the invention, even though others may be a different invention (and product).

### **An Adequate Description – s 40(2)(a)**

The *Patents Act 1990* (Cth) requirement to ‘describe the invention fully, including the best method known to the applicant of performing the invention’<sup>66</sup> is applied to necessitate both a description of the nature of the invention as well as a description of the best method of performing the invention.<sup>67</sup> In general terms, the nature of the invention must be apparent from reading the whole specification,<sup>68</sup> including the claims,<sup>69</sup>

<sup>64</sup> See generally Australian Patents for Plants, above n 16; see for an example of an accepted patent defining the invention by a seed deposit, Australian Standard Patent 769754, above n 22.

<sup>65</sup> *Electric & Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39 (Lord Russell LJ).

<sup>66</sup> *Patents Act 1990* (Cth) s 40(2)(a).

<sup>67</sup> *Universal Oil Products v Monsanto* (1973) 46 ALJR 658, 661 (Gibbs J).

<sup>68</sup> Noting that the Patents Regulations 1991 (Cth), r 3.3(6) provide that ‘[a]n abstract is not taken into account in construing the nature of the invention that is the subject of the specification to which the abstract relates’.

<sup>69</sup> *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 12-13 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).

and the best method of performing the invention requires the complete specification, including the claims,<sup>70</sup> to disclose the best information about how to carry out the invention.<sup>71</sup> In each instance there must be sufficient meaning<sup>72</sup> in the words, drawings and other illustration<sup>73</sup> in the complete specification, at the date the complete specification was filed,<sup>74</sup> for a person skilled in the relevant art<sup>75</sup> to perform the invention.<sup>76</sup> Further, a complete specification must also be able to be followed without any new invention or additions<sup>77</sup> and without prolonged study to resolve any difficulty.<sup>78</sup>

These requirements raise special problems for living organisms that were addressed, in part,<sup>79</sup> in the *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of*

<sup>70</sup> *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 12-13 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).

<sup>71</sup> See *Firebelt Pty Ltd v Brambles Australia Ltd* (2000) 51 IPR 531, 543-545 (Spender, Drummond, Mansfield JJ).

<sup>72</sup> Noting that easily rectifiable mistakes or corrected omissions that can be addressed without any 'inventive faculty' will not invalidate the patent: see *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123, 128 (McTiernan J); notably, process claims probably require greater precision than product claims, 128-129.

<sup>73</sup> Noting that IP Australia accepts photographs and drawings as part of the description requirements, such as photographs of a plant invention: see Australian Patent Office, *Manual of Practice and Procedure* (September 2002), [6.2.2.2] (Vol 2).

<sup>74</sup> *Patents Act 1990* (Cth) s 43(2), unless the Regulations provide a different date; see *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205, 223 (Gummow J); although where 'micro-organisms' are deposited this date may be earlier than the date the complete specification is filed: see *Patents Act 1990* (Cth) s 6.

<sup>75</sup> Noting that it is the meaning of the words (together with the drawings or other illustrations) that determine the adequacy of the description, and not the information a person skilled in the art would derive from the words: see *British Celanese v Courtaulds Ltd* (1935) 52 RPC 171, 196 (Tomlin LJ).

<sup>76</sup> *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 16 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ); this requirement will also be satisfied if a skilled person can 'easily rectify the mistakes and can readily supply the omissions': *AMP Inc v Utilux Pty Ltd* (1971) 45 ALJR 123, 128 (McTiernan J) citing *No-Fume Ltd v Frank Pitchford & Co Ltd* (1935) 52 RPC 231, 243 (Romer LJ).

<sup>77</sup> See *No-Fume Ltd v Frank Pitchford & Co Ltd* (1935) 52 RPC 231, 243 (Romer LJ); see also *Universal Oil Products Co v Monsanto* (1973) 46 ALJR 658, 661 (Gibbs J); *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 17 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).

<sup>78</sup> See *Valensi v British Radio Corporation Ltd* (1973) RPC 337, 375 (Russell, Buckley and Cairns LJJ); *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 17 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).

<sup>79</sup> For an analysis of the limits of deposit requirements for organisms outside the classes of organisms accepted by depositary authorities see Lawson, above n 15.

*Patent Procedure* (Budapest Treaty),<sup>80</sup> and now adopted in the *Patents Act 1990* (Cth).<sup>81</sup> To address the requirement of a full description for 'micro-organisms', the *Patents Act 1990* (Cth) provides:

To the extent that an invention is a micro-organism, the complete specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if the deposit requirements are satisfied in relation to the micro-organism.<sup>82</sup>

The *Patents Act 1990* (Cth) then addresses the circumstances in which deposit of the 'micro-organism' is mandatory,<sup>83</sup> and provides that:

Where: (a) an invention involves the use, modification or cultivation of a micro-organism ... and (b) a person skilled in the relevant art in the patent area could not reasonably be expected to perform the invention without having a sample of the micro-organism before starting to perform the invention; and (c) the micro-organism is not reasonably available to a person skilled in the relevant art in the patent area; the specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if, and only if, the deposit requirements are satisfied in relation to the micro-organism.<sup>84</sup>

However, the term 'micro-organism' is not defined in either the Budapest Treaty or the *Patents Act 1990* (Cth). In practice, this has been resolved:

The Australian Patent Office interprets the term 'micro-organism', as used in the *Patents Act*, to include any biological materials accepted for deposit for the purposes of the Budapest Treaty with a prescribed depository institution in accordance with the rules relating to micro-organisms.<sup>85</sup>

Some prescribed depository authorities accept seeds.<sup>86</sup> Thus, depositing seeds with a prescribed depository authority is sufficient to satisfy the

<sup>80</sup> [1987] ATS 9 (Budapest Treaty).

<sup>81</sup> *Patents Act 1990* (Cth) ss 6, 41, 42 and sch 1; Patents Regulations 1991 (Cth), rr 1.5, 3.23-3.31; see also Australian Patent Office Manual, above n 72, pt 6 (Vol 2).

<sup>82</sup> *Patents Act 1990* (Cth) s 41(1).

<sup>83</sup> Interestingly, IP Australia appears to consider the applicant may select either a description or a deposit: see for example Australian Patent Office Manual, above n 73, [6.1.4] and [6.2.1.1] (Vol 2).

<sup>84</sup> *Patents Act 1990* (Cth) s 41(2); see also *Commonwealth Scientific and Industrial Research Organisation v Bio-Care Technology Pty Ltd* (1999) 45 IPR 483.

<sup>85</sup> Australian Patent Office Manual, above n 73, [6.1.5] (Vol 2); notably, seeds are expressly identified as an example of a 'micro-organism' [6.1.5].

<sup>86</sup> For a complete listing of depository authorities that accept seeds for the purposes of the Budapest Treaty see World Intellectual Property Organisation, *Guide to the Deposit of Micro-organisms under the Budapest Treaty* (2000), 47-49; see also IP Australia, *The Budapest Treaty and Australian Patents* (2002), 1; Australian Patent Office Manual, above n 73, [6.3.1.3] (Vol 2) sets out a list of prescribed depository institution for the purposes of the *Patents Act 1990* (Cth) ss 6 and 41.

*Patents Act 1990* (Cth) requirement that the invention be apparent from reading the whole specification.<sup>87</sup> The deposit of the seeds in the *New Pepper Variety* application meets this IP Australia requirement.

But this deposit is not adequate to satisfy the best method of performance requirements.<sup>88</sup> The question whether a specification adequately describes the best method of performance is a question of fact generally dependent on the evidence of persons skilled in the relevant art.<sup>89</sup> The *Patents Act 1990* (Cth) requirements are not satisfied where this description does not 'provide, expressly or impliedly, to a skilled workman any information as to the method of carrying out the invention',<sup>90</sup> or the specification so clearly fails to disclose a manner of carrying out the invention that no evidence is necessary to show its insufficiency.<sup>91</sup> Where the description provides some disclosure of a method, then it may be valid unless the uncertainty or ambiguity is intentional or incapable of resolution by a skilled addressee applying common sense and common knowledge.<sup>92</sup> The threshold considered by the court is whether:

... the terms of a specification are so ambiguous that its proper construction must always remain a matter of doubt, and in such a case, even if the specification had been prepared in perfect good faith, the duty of the court would be to declare the patent void.<sup>93</sup>

Guidance on achieving these requirements for plant inventions has been provided by IP Australia. Thus, in lodging a patent application IP Australia requires that 'all the breeding methods and crosses to produce the inventive variety must be disclosed'.<sup>94</sup> Where the invented plant variety is a very low probability event, IP Australia notes that 'the issue when considering repeatability is not the numerical probability of

<sup>87</sup> *Patents Act 1990* (Cth) ss 41 and 42; Patents Regulations 1991 (Cth), r 3.23; see also Australian Patent Office Manual, above n 73, [6.1.5] (Vol 2); The Budapest Treaty and Australian Patents, above n 86, 1.

<sup>88</sup> Noting that *Patents Act 1990* (Cth) s 41(1) provides that 'the complete specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if the deposit requirements are satisfied' (emphasis added).

<sup>89</sup> *Universal Oil Products Co v Monsanto* (1973) 46 ALJR 658, 661 (Gibbs J).

<sup>90</sup> *Samuel Taylor Pty Ltd v SA Brush Co Ltd* (1950) 83 CLR 617, 623 (Latham CJ).

<sup>91</sup> See *Commissioner of Patents v Microcell* (1959) 102 CLR 232, 245 (Dixon CJ, McTiernan, Fullagar, Taylor and Windeyer JJ).

<sup>92</sup> *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ).

<sup>93</sup> *Martin v Scribal Pty Ltd* (1954) 92 CLR 17, 59 (Dixon CJ) citing *Natural Colour Kinematograph Co Ltd v Bioschemes Ltd* (1915) 32 RPC 256, 269 (Parker LJ).

<sup>94</sup> Australian Patent Office Manual, above n 73, [6.2.3] (Vol 2).

achieving the specified result, but whether the result can be reproduced to a practical level acceptable to the person skilled in the art'.<sup>95</sup>

By way of example, IP Australia states that chance mutations may not be patentable because of a lack of 'practical repeatability'.<sup>96</sup> Where there has been some selection applied (and presumably this will be satisfied by the slightest evidence of a desired character), then all that is required is a description of how the claimed invention was made,<sup>97</sup> and a statement in the description such as '[i]t is practical<sup>98</sup> to repeat the invention using current state of the art techniques to carry out the number of trials necessary to achieve the desired result'.<sup>99</sup> However, IP Australia considers that the issue of repeatability is unlikely to be at issue when seeds are deposited with a prescribed depositary authority according to the Budapest Treaty,<sup>100</sup> as the invention *per se* has been described.<sup>101</sup>

IP Australia also requires that 'the parents of the variety must be either easily available to the public in Australia (for example, commercially available or in an accessible deposit) or be fully described themselves'.<sup>102</sup> The Budapest Treaty provides a mechanism for accessing samples.<sup>103</sup> Presumably in the present matter the parental varieties were readily available and this requirement would have been satisfied, although there is no formal requirement for the applicant to declare that this requirement has been satisfied.

Applying these standards it seems likely that IP Australia would accept a seed deposited with a prescribed depositary authority as a sufficient description (including a best method) of a plant invention.<sup>104</sup>

<sup>95</sup> Ibid [6.2.4.2] (Vol 2).

<sup>96</sup> Thus,

'in a case involving the "Scarlet Queen Elizabeth" rose, it was held that the process of production of the plant was not sufficiently described because it was a chance genetic mutation. It was estimated that the probability of repeating this mutation was 1 in 100,000,000, which was impractical, if not impossible given the methods of reproduction available at that time'

Australian Patent Office Manual, above n 73, [6.2.4.3] (Vol 2).

<sup>97</sup> Ibid [6.2.4.4] (Vol 2).

<sup>98</sup> Unfortunately, it is unclear what 'practical' means, although 'millions of trials' may be acceptable in some circumstances: above n 73, [6.2.4.4] (Vol 2).

<sup>99</sup> Ibid [6.2.4.4] (Vol 2); see also Australian Patents for Plants, above n 16, 3.

<sup>100</sup> Australian Patents for Plants, above n 16, 3.

<sup>101</sup> See Australian Patent Office Manual, above n 73, [6.3.2] (Vol 2).

<sup>102</sup> Ibid.

<sup>103</sup> Ibid [6.6] (Vol 2).

<sup>104</sup> See generally Australian Patents for Plants, above n 16.

Significantly, such applications have been accepted by IP Australia.<sup>105</sup> The Australian courts, however, have not been required to adjudicate such an application to date.<sup>106</sup> Were the courts required to make such adjudication the same questions about ambiguity as to what has been invented in the *New Pepper Variety* application would likely arise. It is arguable that the specification would be found to be ambiguous, as describing the invention in a way that it might be made after the patent term has expired will always remain ambiguous because it is practically impossible to adequately describe a heterogeneous biological material. This was the problem addressed by requiring a deposit. However, where the deposited material is a heterogeneous biological material resulting from sexual reproduction the deposited materials may not exhibit the desired characters and where those characters are exhibited they may not be expressed in the best genetic background. This is particularly a problem where a competitor might seek to use the deposited seeds after the patent term to develop an improved line that might include the segregating characters of red, sweet, red, low-seeded fruit resembling a Jalapeno pepper in size and shape. Further, repeatability may be an issue where the deposited seeds do not exhibit all of the essential characters of the invention.

### The approach in the United States

Recent developments in the United States provide some clarity to the issues that might face an Australian court and IP Australia, although there have been no decisions in the United States directly on the points raised in this article.<sup>107</sup> The value of the United States decisions is to clearly identify the problems of the deposit requirements for heterogeneous biological materials. However, the granting of a patent for a specification

<sup>105</sup> See for example Australian Standard Patent 769754, above n 22.

<sup>106</sup> Perhaps significantly, in the United States Supreme Court decision in *JEM AG Supply Inc v Pioneer Hi-Bred International Inc* 534 US 124 (2001), and in the primary decision in the United States District Court Northern District of Iowa in *Pioneer Hi-Bred International Inc v JEM AG Supply Inc* 49 USPQ.2d 1813 (Iowa, 1998), the adequacy of the description of a sexually reproducing hybrid seed claimed as '[i]nbred corn seed designated PHP38, having ATCC accession No 75612' (Claim 1; United States Patent 5,506,367, *Inbred Corn Line PHP38*, Joseph Keaschall (1996)) was not considered, with the argument about patent invalidity addressing only the question on summary judgement that sexually reproducing plants were not patentable subject matter within the scope of 35 USC §101 (129; Thomas J).

<sup>107</sup> Notably, the United States Supreme Court decision in *JEM AG Supply Inc v Pioneer Hi-Bred International Inc* 534 US 124 (2001), did not address the issue even though the patents in dispute there defined and described the invention by reference to a deposited seed.

and claims in identical terms in the United States suggests the United States Patent and Trade Mark Office may not itself have resolved these concerns entirely satisfactory.<sup>108</sup>

In the United States the requirements for a standard patent<sup>109</sup> are a written description<sup>110</sup> comprising<sup>111</sup> a description of the claimed invention<sup>112</sup> and a description to enable its reproduction and use,<sup>113</sup> and then separate claims defining the invention and clearly identifying the boundaries of the invention.<sup>114</sup> For living organism inventions, the deposit of biological materials does not necessarily satisfy the written description requirements,<sup>115</sup> although it does satisfy the enablement requirement.<sup>116</sup> In

<sup>108</sup> See *New Pepper Variety*, above n 19.

<sup>109</sup> This means patents under 35 USC §101; different rules apply for plant patents under the *Plant Patent Act* (35 USC §§161-164).

<sup>110</sup> 35 USC §112 ¶ 1:

‘The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention’.

<sup>111</sup> ‘This statutory language [of 35 USC §112 ¶ 1] mandates satisfaction of two separate and independent requirements: an applicant must both describe the claimed invention adequately and enable its reproduction and use’: *Amgen Inc v Transkaryotic Therapies Inc* 314 F.3d 1313, 1330 (Fed Cir 2003); there is also an ancillary requirement of ‘possession’: see *Vas-Cath Inc v Mahurkar* 935 F.2d 1555, 1561 (Fed Cir 1991); *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 969 (Fed Cir 2002; Enzo II).

<sup>112</sup> This will include ‘a written description of the invention’ and ‘the best mode contemplated by the inventor of carrying out his invention’: 35 USC §112 ¶ 1; this is equivalent to the requirements of the *Patents Act 1990* (Cth) s 40(2)(a).

<sup>113</sup> This is the requirement of an adequate disclosure to a person skilled in the relevant art of ‘the manner and process of making and using’ the invention: 35 USC §112 ¶ 1; there is no direct equivalent in the *Patents Act 1990* (Cth), although the description of the nature of the invention required by *Patents Act 1990* (Cth) s 40(2)(a) has been interpreted to require sufficient meaning in the words of the description that a person skilled in the art could perform the invention: see *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 16 (Gleeson CJ, McHugh, Gummow, Hayne and Callinan JJ).

<sup>114</sup> 35 USC §112 ¶ 2: ‘The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention’: see *Solomon v Kimberly-Clark Corp* 216 F.3d 1372 (Fed Cir 2000); this is equivalent to the requirements of the *Patents Act 1990* (Cth) ss 40(2)(b) and (3).

<sup>115</sup> *In re Lundak* 773 F.2d 1216, 1217 (Fed Cir 1985); the written description being satisfied by the specification disclosing ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention’: *Lockwood v American Airlines Inc* 107 F.3d 1565, 1572 (Fed Cir 1997).

<sup>116</sup> *Ajinomoto Co v Archer-Daniels-Midland Co* 228 F.3d 1338, 1345-46 (Fed Cir 2000); although it is not necessary to satisfy the enablement requirement: see *Amgen Inc v Chugai Pharmaceutical Co* 927 F.2d 1200, 1210 (Fed Cir 1991).

a similar fashion to the *Patents Act 1990* (Cth), the deposit of biological materials, including seeds, is required if it is necessary to satisfy the written description requirements.<sup>117</sup> Unfortunately, the precedent in the United States about the role of a deposit in satisfying the written description has been under dispute with various conflicting decisions. As a generalisation, the dispute concerns the requirement that the written description sufficiently distinguish the invented materials from other materials<sup>118</sup> and that the inventor be ‘in possession’ of the invention.<sup>119</sup> The court’s attention to these disputes provides some insights into the problems with deposits.

The Court of Appeals for the Federal Circuit in *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp*<sup>120</sup> considered the adequacy of a deposit of a Porcine Reproductive Respiratory Syndrome (PRRS) virus ATCC-VR2332 with a depositary authority. The claim in issue was ‘[t]he method as recited in claim 1 wherein the simian cell line is MA-104’<sup>121</sup> where the term in claim 1 ‘swine infertility and respiratory syndrome virus, ATCC-VR2332’ was in dispute.<sup>122</sup> In construing the meaning of the term, Schering-Plough argued that the claimed virus was confined to only ‘disease causing’ viruses designated ATCC-VR2332.<sup>123</sup> The court consulted the specification<sup>124</sup> to find that ‘the term “ATCC-VR2332” did not by itself demand pathogenicity’<sup>125</sup> as the specification referred to

<sup>117</sup> See United States Patent and Trade Mark Office, *Deposit of Biological Materials for Patent Purposes* 54 Fed Reg 34864, 34879 (22 August 1989); 37 CFR §§1.801-1.809.

<sup>118</sup> The court in *Regents of the University of California v Eli Lilly and Co* 119 F.3d 1559, 1567-1568 (Fed Cir 1997) deciding that the nucleotide sequence itself was necessary to distinguish between a broad function (vertebrate or mammalian insulin cDNA) and what the actual invention was (rat insulin cDNA).

<sup>119</sup> The court in *Vas-Cath Inc v Mahurkar* 935 F.2d 1555, 1563 (Fed Cir 1991) citing *Lockwood v American Airlines Inc* 107 F.3d 1565, 1572 (Fed Cir 1997) where the court considered that ‘all that is necessary to satisfy the description requirement is to show that one is “in possession” of the invention’.

<sup>120</sup> 320 F.3d 1339 (Fed Cir 2003).

<sup>121</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1344-1345 (Fed Cir 2003).

<sup>122</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1347 (Fed Cir 2003).

<sup>123</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1347-1348 (Fed Cir 2003).

<sup>124</sup> Noting that ‘[e]ven if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognise what is claimed’: *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 969 (Fed Cir 2002; Enzo II), 968.

<sup>125</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1348 (Fed Cir 2003).

‘modified or attenuated live ATCC-VR2332’.<sup>126</sup> Boehringer argued that ‘the term “ATCC-VR2332” should be understood as a “prototype” or “generic” term for all PRRS viruses, rather than as a reference to the deposited strain’.<sup>127</sup> The court concluded:

We find Boehringer’s arguments no more persuasive than Schering’s on this point. Boehringer chose to claim its virus using the term ‘ATCC-VR2332’, a term on its face referring to a particular ATCC deposit. Boehringer did not use the broader term ‘PRRS virus’, nor did Boehringer attempt to claim the virus in terms of the more general functional and structural properties disclosed by the specification. Boehringer did not choose to define the term ‘ATCC-VR2332’ in the specification, nor did Boehringer state that ATCC-VR2332 was a ‘generic’ or ‘prototype’ virus, nor did Boehringer assert that viruses related to but not identical to the isolated strain were within the scope of the invention. These choices must be held against it. We therefore conclude that the district court<sup>128</sup> properly construed ‘ATCC-VR2332’ to refer to the strain of virus deposited with the ATCC.<sup>129</sup>

The earlier District Court decision sets out the arguments which it considered in reaching its decision, consulting the body of the specification to clarify its interpretation of the term, that ‘the preamble language, “swine infertility and respiratory syndrome virus, ATCC-VR2332” limits the claim to the PRRS strain deposited’.<sup>130</sup> In reaching this conclusion the court expressly rejected Boehringer’s contention that the deposited virus ATCC-VR2332 was

understood by those skilled in the art to be a name associated with the first PRRS virus isolated in North America, and [is] therefore, representative of all PRRS viruses’ and ‘is merely representative of the invention and permits the public to make and use the invention without having to ‘re-discover’ the organism.<sup>131</sup>

Unfortunately, the court in *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* did not expressly explain what functions or properties must be shown to establish that another virus meets this

<sup>126</sup> See *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1348 (Fed Cir 2003).

<sup>127</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1348 (Fed Cir 2003).

<sup>128</sup> *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 984 F.Supp 239, 249 (NJ 1997).

<sup>129</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1348 (Fed Cir 2003).

<sup>130</sup> *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 320 F.3d 1339, 1344-1345 (Fed Cir 2003).

<sup>131</sup> *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 320 F.3d 1339, 1344-1345 (Fed Cir 2003).

definition. Further, the PRRS virus was presumably a homogeneous culture<sup>132</sup> and so the court did not provide any guidance as to how to define the invention represented in a heterogeneous culture. However, some guidance may be gleaned from the court's analysis of the infringement claims where a process patent is claimed by reference to a deposited sample. Relevantly, Schering-Plough had independently developed an attenuated PRRS virus for use as a vaccine.<sup>133</sup> Boehringer alleged that Schering-Plough's virus was prepared by a process that infringed its method claim.<sup>134</sup> While literal infringement was not necessary to decide based on the construction of the claims,<sup>135</sup> the question of infringement under the doctrine of equivalents was considered.<sup>136</sup> In the lower court a jury had concluded that a preponderance of evidence showed that the Schering-Plough's ATCC-VR2525 virus was equivalent to Boehringer's ATCC-VR2332 virus.<sup>137</sup> On appeal the question was whether '[u]nder the doctrine of equivalents, a claim limitation not literally met may be satisfied by an element of the accused product if the differences between the two are "insubstantial" to one of ordinary skill in the art'.<sup>138</sup> This may include the assessment of 'whether the element in the accused device "performs substantially the same function in substantially the same way to obtain the same result" as the claim limitation'.<sup>139</sup> Schering-Plough had presented evidence that its virus could 'perform other functions in different ways to yield a different

<sup>132</sup> In this case the deposited PRRS virus had been passaged eight times: see *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, (Fed Cir 2003).

<sup>133</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1343 (Fed Cir 2003).

<sup>134</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1344 (Fed Cir 2003).

<sup>135</sup> See *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1350 (Fed Cir 2003) where the court found no literal infringement because the Schering-Plough's vaccine production process relied on time rather than Boehringer's observable cytopathic effects and Schering-Plough's ATCC-VR2525 virus was not Boehringer's deposited ATCC-VR2332 virus.

<sup>136</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1350 (Fed Cir 2003).

<sup>137</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1350 (Fed Cir 2003); see also *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp*, 34-36 (NJ 1997)

<sup>138</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1351 (Fed Cir 2003) citing *Warner-Jenkinson Co Inc v Hilton Davis Chemical Co* 520 US 17, 40 (1997).

<sup>139</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1351 (Fed Cir 2003) citing *Graver Tank & Mfg Co v Linde Air Products Co* 339 US 605, 608 (1950).

result', didn't induce illness it vaccinated pigs,<sup>140</sup> react with particular monoclonal antibody differently,<sup>141</sup> grew poorly in pig lung macrophages,<sup>142</sup> had 73 nucleotide (insubstantial) differences,<sup>143</sup> all suggestive and markers of a different strain.<sup>144</sup> The court considered these differences were not relevant because 'these facts are simply not relevant to the equivalence inquiry because those properties of the virus are not pertinent to a method of growing and isolating the virus as defined by claim 2'.<sup>145</sup> Although the court did concede that 'it may be reasonable to assume that genetic similarity is a relevant comparison between the viruses for the purposes of the claimed method', but in this case the jury inquiry had been presented with expert evidence that the differences in viral genomes was 'insignificant' and it was open on this evidence to conclude that the genetic difference in the context of the claimed method were 'insubstantial'.<sup>146</sup> This is probably significant as the court's conclusion in effect recognises that Boehringer's deposited ATCC-VR2332 virus was, as a question of fact, equivalent (not insubstantially different) to Schering-Plough's ATCC-VR2525 virus. But an important nuance was that the equivalence related only to using the ATCC-VR2525 virus according to the claim in Boehringer's patent. That is, making PRRS virus in 'simian cell line MA-104' according to Claim 1.<sup>147</sup> The effect of this decision is that the describing and the claiming of an invention through the deposit of materials confines the invention to that deposit and anything equivalent (not insubstantially different), recognising that two different deposits may be equivalent as a result of the scope of the claims.

<sup>140</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1351 (Fed Cir 2003).

<sup>141</sup> Interestingly, this had been a ground for accepting a patent for Schering-Plough's ATCC-VR2525 virus over the prior art: see *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 984 F.Supp 239, 249 (NJ 1997).

<sup>142</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1351 (Fed Cir 2003).

<sup>143</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1352 (Fed Cir 2003).

<sup>144</sup> In a lower court Schering-Plough had also identified differences in glycosylation patterns: see *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 984 F.Supp 239, 249 (NJ 1997).

<sup>145</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1352 (Fed Cir 2003).

<sup>146</sup> *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1352 (Fed Cir 2003).

<sup>147</sup> See *Boehringer Ingelheim Vetmedica Inc v Schering-Plough Corp* 320 F.3d 1339, 1351 (Fed Cir 2003); see also *Boehringer Ingelheim Animal Health Inc v Schering-Plough Corp* 984 F.Supp 239, 249 (NJ 1997).

More recently, decisions in *Enzo Biochem Inc v Gen-Probe Inc*<sup>148</sup> concerned the written description of a recombinant DNA molecule from *Neisseria gonorrhoeae* within an *Escherichia coli* bacterial host deposited with a depositary authority.<sup>149</sup> In essence Enzo was arguing that the written description requirement for nucleotide sequences set out in *Regents of the University of California v Eli Lilly & Co*<sup>150</sup> should not apply as Enzo had reduced the invention to practice and deposited the derived biological materials.<sup>151</sup> In response, Gen-Probe argued that the patent described the claimed nucleotide sequences only by their function and that this was inadequate to meet the written description requirements even though the nucleotide had been deposited.<sup>152</sup> Significantly, the court adopted the United States Patent and Trade Mark Office's Guidelines (PTO Guidelines) for a written description stating:

that the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics'.<sup>153</sup>

Applying these requirements, the court considered whether the deposited nucleotide sequences constituted an adequate description of those sequences, and then whether the description requirement had been met for all the claims on the basis of the functional ability of the claimed nucleotide sequences to hybridise to strains of *N. gonorrhoeae* that are accessible by deposit.<sup>154</sup> In addressing these issues the court held that a 'reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the

<sup>148</sup> 285 F.3d 1013 (Fed Cir 2002; Enzo I) and 323 F.3d 956 (Fed Cir 2002; Enzo II); Enzo I was vacated by Enzo II that was a complete rehearing that reversed the earlier decision.

<sup>149</sup> See *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 969 (Fed Cir 2002; Enzo II).

<sup>150</sup> 119 F.3d 1559 (Fed Cir 1997); the court held that a claim to a micro-organism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA as this did not show that the inventors had possession of human insulin cDNA (at 1567).

<sup>151</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 963 (Fed Cir 2002; Enzo II).

<sup>152</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 963 (Fed Cir 2002; Enzo II).

<sup>153</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 963 (Fed Cir 2002; Enzo II); see also United States Patent and Trade Mark Office, *Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶1 'Written Description' Requirement* 66 Fed Reg 1099, 1106 (5 January 2001).

<sup>154</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 964 (Fed Cir 2002; Enzo II).

deposited material'.<sup>155</sup> On the facts of this case however, these deposited nucleotide sequences (between 850 and 1300 nucleotides long) were merely representative of the class of claimed nucleotide sequences as the claims extended to sub-sequences (being 'greater than 12 nucleotides'), mutated variations and mixtures raising the prospect that the deposit was adequate to describe *all* those sequences to one of skill in the art.<sup>156</sup> The court considered that as the claimed nucleotide sequences preferentially bound genomic DNA of the deposited *N. gonorrhoeae* strains and had a complementary structural relationship with that DNA, then those sequences might be adequately described.<sup>157</sup> Unfortunately, the court considered this a question of fact (being an issue of enablement) and left the matter for decision on remand, stating that the issue was:

'whether one of skill in the art would find the generically claimed sequences described on the basis of Enzo's disclosure of the hybridisation function and an accessible structure, consistent with the PTO Guidelines. If so, the written description requirement would be met'.<sup>158</sup>

Unfortunately, Enzo and Gen-Probe settled the remanded case out of court,<sup>159</sup> leaving uncertain the potential scope of the claim the deposited sequences lawfully allowed. In particular this decision leaves open the prospect that a mere deposit will replace the need to adequately describe an invention setting out its structure and function and left open the problem of heterogeneous deposited materials.

*Enzo Biochem Inc v Gen-Probe Inc* also addressed the dispute about the requirement that the inventor be 'in possession' of the invention.<sup>160</sup> Enzo argued that, by disclosure in the specification that the claimed invention had been reduced to practice by the three deposited sequences, it had

<sup>155</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 965 (Fed Cir 2002; Enzo II); this has subsequently been applied, see for example *University of Rochester v GD Searle & Co Inc* 249 F.Supp.2d 216, 233 (WDNY 2003) where the court ordered summary judgement after considering whether there was an adequate written description where a compound that was necessary to practice a claimed method of treatment described only in terms of its function, and where the only means provided for finding the compound was a trial-and-error process. The court noted that the motion for summary judgment that the patent was invalid for failure to meet the written-description requirement was denied.

<sup>156</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 966 (Fed Cir 2002; Enzo II).

<sup>157</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 968 (Fed Cir 2002; Enzo II).

<sup>158</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 968 (Fed Cir 2002; Enzo II).

<sup>159</sup> See Paula Davis, 'Questioning the Requirement for Written Description: Enzo Biochem v Gen-Probe and Overly Broad Patent Cases' (2004) 37 *Indiana Law Review* 467, 469.

<sup>160</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 968-970 (Fed Cir 2002; Enzo II).

necessarily adequately described the invention.<sup>161</sup> The court rejected this argument clarifying that '[a] showing of "possession" is ancillary to the statutory mandate [of a written description] and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention'.<sup>162</sup> The court did, however, acknowledge that the 'in possession' inquiry was useful in claiming entitlement to an earlier filing date.<sup>163</sup> This was a significant outcome as it establishes that the description requirement must be expressly addressed in the specification, albeit through a deposit.

### Conclusions

Central to the justification for a patent franchise under the *Patents Act 1990* (Cth) is an adequate disclosure both defining the invention so that competitors can avoid infringement and describing its nature and operation so that it might be performed after the term has expired. These are fundamental requirements that go to the core policy objectives of patent privileges and without which the high social costs (and anti-competitive effects) are most likely unwarranted and unjustified. With the expansion of patent privileges into the realms of living organisms, the description requirements have been subjected to considerable strain. This, in part, has been addressed by including deposit requirements as a sufficient description, although the scheme under the Budapest Treaty is, arguably, more suited to homogeneous, asexually reproduced biological materials and was primarily designed to satisfy concerns about reproducing low frequency events in desirable strains of microscopic micro-organisms (principally bacteria).<sup>164</sup> The Budapest Treaty deposits do not, however, adequately address the concern about sufficiently describing heterogeneous, sexually reproduced materials such as seeds, where the deposit is a representative sample of a population, some of which *might* include the invention. Further, the various and different genetic backgrounds of the deposited seeds may not provide the 'best' example of the invention for subsequent use by competitors. The analysis

<sup>161</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 968-969 (Fed Cir 2002; Enzo II).

<sup>162</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 969 (Fed Cir 2002; Enzo II).

<sup>163</sup> *Enzo Biochem Inc v Gen-Probe Inc* 323 F.3d 956, 969 (Fed Cir 2002; Enzo II).

<sup>164</sup> Thus,

'[i]n the case of an organism isolated from soil, for instance, and perhaps "improved" by mutation and further selection, it would be virtually impossible to describe the strain and its selection sufficiently to guarantee another person obtaining the same strain from soil himself. In such a case, the micro-organism itself might be considered to be an essential part of the disclosure'

World Intellectual Property Organisation, above n 86, 1.

of the complete specification and claims of the *New Pepper Variety* in this article highlights these kinds of problems.

In addition to requiring a sufficient description, the claims are central to defining the scope of the patent privileges. This is particularly important for competitors seeking to substitute and imitate the invention during the term of the patent privileges and invest in potentially useful developments that promote further beneficial competition. Where claims are made to a deposited heterogeneous, sexually reproduced material, such as the seeds, the uncertainty arises from competitors knowing exactly what has been claimed as the deposited seeds define a sample of a population with a range of characteristics. As the *New Pepper Variety* patent claims show, the consequence of such claims is to make using the parental varieties always subject to a possible claim of infringement as using those varieties can result in seeds similar (certainly ‘not insubstantially different’) to those deposited merely by making the cross. In some circumstances this may be of minimal impact as the *Patents Act 1990* (Cth) expressly provides a partial defence for innocent infringement, although this defence is confined to circumstances where the infringer ‘was not aware, and had no reason to believe, that a patent for the invention existed’<sup>165</sup> affecting the quantum of damages, but not the award of an injunction.<sup>166</sup> In other circumstances, (and presumably most competitors would be aware of their competitors’ patents), the inability to identify clearly a potential infringing seed resulting from using those parental crosses prevents their use entirely by competitors, in effect commodifying those parental varieties for the patent holder. This is particularly concerning as competitors could use the same parental varieties (in many cases they are likely to be the limited numbers of elite germplasm varieties) to make other useful crosses with other, different and desirable characters. Further, the broad claim in the *New Pepper Variety* patent potentially extends to infringement by any crosses of *Capsicum annum* which result in plants that are broadly described as having fruit that is red, sweet, low-seeded and resembling a Jalapeno pepper in fruit size and shape, as those terms are used in the complete specification, vastly extending the potential for infringement by competitors. It is not certain that this is desirable, in encouraging competitors to invest in competing varieties that might include such broadly and uncertainly defined characters.

The decisions in the United States suggest that it is the deposited materials that are the invention, although the potential limits remain

<sup>165</sup> *Patents Act 1990* (Cth) s 123(1).

<sup>166</sup> *Patents Act 1990* (Cth) ss 122 and 123(1) and (3).

uncertain. In the context of the *New Pepper Variety* application, this suggests that the deposited seeds themselves are the invention. If this approach is correct then the definition requirements of the *Patents Act 1990* (Cth) are easily met by confining the scope of the claims to just the deposited seeds, although correspondingly, making an infringement action almost impossible to establish unless the deposited seeds were used. This seems an unlikely outcome, thus it seems more likely that the claims apply more broadly to seeds that correspond with those in the deposit. However, as the *New Pepper Variety* application shows, identifying the boundaries of what is claimed by a sexually produced seed will always remain ambiguous because it is practically impossible to adequately define a heterogeneous biological material in a way that 'others may know the exact boundaries of the area within which they will be trespassers'.<sup>167</sup> For competitors the main concern will again be to distinguish their invented plants from those already invented. This might be ameliorated in part by the claims being required to expressly articulate the essential integers of the invention, including at the very least the desirable characters, whereupon a competitor might have a better chance of avoiding infringement of the invented plants.

Most concerning, perhaps, is the potential of deposit claims like those in the *New Pepper Variety* application to limit the development of improvements to elite germplasm varieties. The increasing reduction in the diversity of crop and forage plants<sup>168</sup> and the development of a restricted number of elite germplasm varieties<sup>169</sup> means that traditional plant breeders and those developing new characters with molecular techniques are likely to focus their attention increasingly on the same or similar elite germplasm varieties. Broad claims like those in the *New Pepper Variety* application are likely to be an incentive to plant breeders and developers to focus on germplasm varieties to which they have access (such as through ownership of the patent privileges), and as a disincentive to use varieties that require negotiated access (either through high license fees for possible infringement or even refused access).<sup>170</sup> In taking advantage of the broader range of biodiversity available to develop

<sup>167</sup> *Electric & Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39 (Lord Russell LJ).

<sup>168</sup> Food and Agriculture Organisation of the United Nations, *The State of the World's Plant Genetic Resources for Food and Agriculture* (1998), 33.

<sup>169</sup> Food and Agriculture Organisation of the United Nations, above n 168, 33-34.

<sup>170</sup> See for example Charles Lawson, 'Patents and the CGIAR System of International Agricultural Research Centres' Germplasm Collections under the International Treaty on Plant Genetic Resources for Food and Agriculture' (2004) 55 *Australian Journal of Agricultural Research* 307, 310-311.

improved useful plants, this may not be the most desirable set of incentives. In Australia, this is likely to be a significant concern as the available elite germplasm varieties will, in most circumstances, be required to be further enhanced to suit Australian particular agricultural and environmental circumstances.<sup>171</sup>

The *New Pepper Variety* patent application considered in this article suggests that depositing seeds, and other heterogeneous biological materials, may not be adequate either to define the invention so that competitors can avoid infringement or to describe the invention to ensure that it can be performed after the patent term has expired. If this is correct then broad claims such as that represented by the *New Pepper Variety* patent application should be carefully considered to ensure that the objectives of the *Patents Act 1990* (Cth) are achieved. Unless the objectives of the definition and description requirements in the *Patents Act 1990* (Cth) are met the patent franchise cannot be justified as more effective competition in the long term is unlikely to be achieved while loss of competition in the short term will be unnecessarily promoted.

<sup>171</sup> For examples and further analysis see Charles Lawson, 'Patents and Plant Breeder's Rights Over Plant Genetic Resources for Food and Agriculture' (2004) 32 *Federal Law Review* 107.

**Box 1: Plant sex**

Sex in plants is the fusion of the male and female parts of the plant to produce an offspring. This biological process of reproduction requires several steps in division and re-arrangement of the plant's genes (known as meiosis) and then fusion of the male (pollen) and female (ovum) to produce a seed. The genes are the units controlling particular inherited characteristics of the individual.

The significance of the division and re-arrangement of the plant's genes (meiosis) is to reduce the plant's compliment of genes into half so that the fusing male and female parts will then form a complete compliment of genes, and to combine genes from the parents into a new arrangement in the seeds. The resulting seeds will then have a complete component of genes and, except in vary rare cases, a new arrangement of those genes as well.

Thus 'heterogeneous biological materials' with respect to 'sexually produced seeds' means that the biological materials making up those seeds are comprised of elements (including genes) from both the male and female parents. Significantly, each sexually produced seed will have a unique arrangement of genes and a sample of seeds from any fusion of male pollen and female ovules will each have a different arrangement of genes, except in very rare cases.

The key events are gene duplication during Interphase, the re-arrangement of the genes during Prophase 1 and then two rounds of cell divisions during Telophase 1 and 2. During the re-arrangement genes contributed from each grandparent are swapped (represented by the swapping of black and white portions of the chromosomes and the black and white chromosomes) and these are then carried through to the pollen and ovum. These events (meiosis) happens in each parent so that the resulting offspring will, except in very rare cases, have a novel arrangement of genes, half from each parent, with that parent's half being a novel re-arrangement of the grandparents' genes (including chromosomes).