

Australian Patent Office

Examination Practice following the High Court decision in *D'Arcy v Myriad Genetics Inc*

Background

On 7 October 2015 the High Court delivered judgment in *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

The decision related to Myriad's patent (686004) on the isolated nucleic acid sequences encoding the BRCA1 mutant polypeptide and to methods of testing for the presence of mutations of the representative BRCA1 gene, and thus an increased likelihood of developing breast or ovarian cancer. The High Court was asked to decide whether claims 1-3, directed to the isolated BRCA1 nucleic acid, defined patent eligible subject matter (i.e. a manner of manufacture).

The High Court unanimously decided that claims 1-3 did not define a manner of manufacture. The Court found that, while formulated as claims to a product (i.e. a nucleic acid molecule), the substance of the invention was the information embodied in the sequence of nucleotides of the molecule. The Court decided that the information was an inherent part of the molecule and not "made" (ie created or modified) by human action.

The Court made clear that it was not concerned with "gene patenting" generally and did not make any finding with respect to the remaining claims of the patent.

In considering the High Court's decision and particularly the majority it is apparent that the Court:

- Rejected a formalistic approach to the law of manner of manufacture and a narrow interpretation of its decision in *NRDC*.
- Focused on the substance rather than merely the form of the claimed invention.
- Considered circumstances where the claimed invention departed from established bounds of the concept of manner of manufacture.
- Articulated considerations that apply when a "new class of claim" is involved.

The majority did not deliberate about "products of nature" versus "artificially created products" but found that, in a case where the substance of the claimed invention was genetic information that was not "made", the claiming of the alleged invention as an isolated product did not confer eligibility. The substance was outside the established bounds of patentability and extending the concept of manner of manufacture to that subject matter was not justified.

Practice

In general the law is to be applied on a case by case basis taking into account the principles and approach taken by the High Court. Subject to other requirements of patentability (eg utility, novelty, inventiveness) consideration needs to be given to the extent to which the claimed invention in substance falls within established categories of eligible subject matter (to which the principles of *NRDC* are relevant) and, if not, whether other considerations articulated by the Court apply.

In considering these matters it is useful to ask:

1. What is the substance of the claim (not merely its form)?
2. Has the substance of the claim been "made" or changed by man, or is "artificial"?
3. Does the invention have economic utility?
4. Does the invention as claimed represent a new class of claim?

The substance of the claim

As stated above, the first step is to identify the substance of the claim. The specification, including the claims, provides the information to do this. Relevant factors include:

- The form of words and breadth of the claim.
- The size of the class of compounds covered by the claim.
- Does the compound embody or convey genetic information that is of importance to the utility of the claimed invention.
- The emphasis of the claim.
- What did the applicant invent, is the product a step along the way to a process or method that is the real invention.

Was the substance of the claim "made"

Determining whether the substance of the claim is "made" or is "artificial" involves a comparison between the state of affairs before the invention, and the state of affairs as a result of the invention. Relevant factors include:

- Whether the substance of the claim was "made" (ie created or modified, by human action). It is not enough that the subject matter of the claim is artificial.
- What are the physical differences between the claim and the natural state.
- What was the labour required to produce the product.
- "Made" can include created or modified but not merely through replication.
- Isolation or purification can represent making or modification when the substance of a claim is properly directed to a chemical product.

Utility

The requirement for economic utility is set out in the decision in *NRDC*.

New class of claim

When on the basis of the consideration above or otherwise it becomes apparent that a claim in substance relates to a new class involving a significant new application or extension of the principles of patentability, the Commissioner must consider other factors (See *Myriad* at [28]).

To decide whether a claim relates to a new class, it is not relevant that patents have previously been granted for similar subject matter. Examiners should take into account categories of alleged inventions that the Courts have previously dealt with and whether that subject matter has been rejected.

In general the Courts have indicated that, subject to other requirements, patents are available for products, methods of making and using products, and methods that otherwise result in a new and useful effect. Technical subject matter that has been previously considered by Courts without rejection include:

- Recombinant or isolated proteins.
- Pharmaceuticals and other chemical substances.
- Methods of treatment.
- Methods of applying herbicides.
- Applications of computer technology.

Claims to plants and micro-organisms should be considered carefully as there are significant factors supporting eligibility of this subject matter. These include the terms of the *Patents Act*, including provisions implementing the Budapest Treaty, the decision of the High Court in *The Grain Pool of WA v The Commonwealth* [2000] HCA 14 and treaty obligations.

Consequently, such claims are not to be considered to fall within a new class merely because they are directed to plants or micro-organisms. Rather they are to be examined against normal requirements including whether what is in substance claimed is “made” in a sense indicated above.

Aside from the subject matter rejected in the *Myriad* case, the Courts have excluded a range of other subject matter including the fine arts, mere schemes, abstract ideas and mere intellectual information - See Part 2.9.2 of the *Manual of Practice and Procedure*.

Where it is apparent that the substance of the invention lies outside an established category of patent eligible subject matter, examiners should object. The matter may only be resolvable in the context of a hearing or on appeal to the Federal Court.

Application

Where the substance of a claimed invention falls within an established category, is for a product made, or a process producing an outcome as a result of human action, and has economic utility it will meet the basic manner of manufacture requirement. Other considerations, such as whether an invention is lacking on the face of the specification or is subject to statutory exclusions, may still apply according to established practice - see Parts 2.9.2 and 2.9.3 of the *Manual of Practice and Procedure*.

Following the High Court’s decision claims to the following subject matter are clearly excluded because in substance they can only be considered as a claim to genetic information that is not made:

- Isolated naturally occurring nucleic acid molecules whether:
 - DNA or RNA.
 - Human or non-human.
 - Coding or non-coding.

Claims to the following are excluded where they merely replicate the genetic information of a naturally occurring organism:

- cDNA and synthetic nucleic acids.
- Probes and primers.
- Isolated interfering/inhibitory nucleic acids.

Subject matter of this type may be patentable where the utility of the invention lies in genetic information that has been “made” (eg non-naturally occurring chimeric nucleic acid).

Other biological inventions should be considered according to the same general principles above. If what is claimed properly falls within the requirements for existing categories of products and processes (eg is not for or merely replicates the genetic information of a naturally occurring organism) it will be patent eligible.