I. Legal framework

1. On April 1, 1995, came into force the new Netherlands Kingdom Patent Act (ROW 1995) whereby the former examination patent system was changed over into a registration patent system. Dutch patent applications filed under ROW 1995 will not be subjected to a substantive examination of patentability. If formal requirements are complied with, the Netherlands Patent Office (BIE) will grant a Netherlands patent on the application. The main reason for the change in patent system was the existence of the European Patent Office (EPO) examining most applications relevant for the Netherlands and in particular in relation to patent applications in new technical fields such as biotechnology.

2. The EPO only grants a European patent (which may result in a Dutch (European) patent upon designation of the Netherlands) after a material examination of the patentability of the invention disclosed in the European patent application.

3. Nullity proceedings before the competent Netherlands Patent Court against a Dutch patent granted by BIE under ROW 1995 are only admissible if accompanied by an advice of BIE in relation to the applicability of the nullity grounds mentioned in Article 75(1) ROW 1995.

4. Recently, the EPO implemented the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions. The Directive will be used as a supplementary means for interpreting the legal protection of biological inventions. This Directive is also in a process of implementation in ROW 1995, although the Netherlands Government filed a request for nullification of this Directive at the Court of Justice. However, eventually ROW 1995 will be in line with the Directive.

---

1 Decision of the Administrative Council of 16 June 1999. This Decision will enter into force on September 1, 1999 (Official Journal EPO 1999, 573).
5. The above implies that at present ROW1995 and Case Law based thereon have no direct bearing on the patentability of EST's, SNP's, genomic DNA, and genomes, and that patents for EST's, SNP's, genomic DNA and genomes, and which patents are relevant for the Netherlands, are to be examined by the EPO following their Guidelines and Case Law and for the future of the Directive.

6. Finally, it is noted that in relation to biotechnological patents judgements of the competent Netherlands District Court and Appeal Court are generally in harmony with the Case Law of the EPO.

7. In summary, the legal frame work in the Netherlands for biotechnological inventions is very similar to that set by the European Patent Convention (EPC) and the Directive.

II. Answers to the proposed questions

1. Introduction

8. The Netherlands working group starts from the basic opinion that EST's, SNP's and genomic DNA and genomes are nucleotide sequences and here are to be considered as physical entities. No reasons are available against a treatment of these nucleotide sequences as ordinary chemical compounds. Article 5 of the Directive, in particular, does not provide a limitation to this basic opinion. Accordingly, their patentability should be examined in the same manner as the patentability of chemical compounds. Hence, the same standard patentability requirements for chemical compounds should apply also for EST's, SNP's, genomic DNA and genomes.

2. Public Policy

Question 3.1(a)³

"Are EST's, SNP's and genomes inventions the patenting of which is contrary to "ordre public" or morality (TRIPS, Article 27.2)?"

9. TRIPS, Article 27.2 allows members to exclude from patentability inventions of which commercial exploitation is against "ordre public" or morality. Within the Dutch lagen frame work (Article 3(a) ROW 1995 and Article 53(a) EPC) patents shall not be granted for inventions of which publication or use is contrary to "ordre public" or morality. The Dutch working group is not aware of any general reasons why publication or use of these DNA sequences is contrary to "ordre public" or morality.

10. It can only be decided on a case by case basis whether publication or a specific use of a specific DNA sequence is contrary to "ordre public" or morality.

---

² SNP's are considered as embodied in a population of nucleotide sequences possessing polymorphism at a particular site of these sequences.

³ The questions are numbered following the paragraph numbering of the Working Guidelines for Question 150.
**Question 3.1(b)**

"Are patent offices the correct place to determine these questions and do they have sufficient resources to make such decisions?"

11. Pursuant to Article 3(a) ROW 1995 and Article 53(a) EPC BIE and EPO respectively are the competent institute to consider morality when patenting inventions. In the Decisions T19/90 (Harvard/Oncomouse) and T356/93 (Plant Genetic Systems/glutamine synthetase inhibitors) the Board of Appeals of the European Patent Office dealt with the issue of morality. These Decisions (and the Interlocutory Decision of the Opposition Division following T19/90) show that the European Patent Office appears to have sufficient resources to make such decisions on morality and "ordre public". But such decisions should be based on information available to the EPO and/or entered into the proceedings before the EPO.

4 Utility

**Question 3.2**

"What level of utility should be required of patents for EST's, SNP's and genomic DNA?"

12. The Dutch working group is of the opinion that utility is to be understood as industrial application and more specifically as the exploitation of a (biological) function performed by the respective DNA sequence and/or by the protein encoded by the DNA sequence.\(^4\)

13. As indicated above the Netherlands working group is of the opinion that inventions and patents in relation to EST's, SNP's and genomic DNA should comply to the same standards for patentability as apply for other inventions in particular inventions relating to chemical compounds. The requirement for industrial application as laid down in Article 7 ROW 1995 and Article 57 EPC, is complied with when the respective EST's, SNP's and genomic DNA can be made or used in any type of industry on the basis of the disclosure in the patent specification.

14. When there are no reasons to doubt whether the respective EST's, SNP's and genomic DNA can be made or used industrially, then these inventions/patents comply with the standard level of industrial application as required for any invention, in particular chemical compound inventions.

5 Invention

**Question 3.3**

"Is an EST or SNP an "invention" at all?"

15. The Dutch working group is of the opinion that EST's and SNP's and also genomic DNA, cannot be considered as mere pieces of information as is indicated in the preamble to question 3.3 (see paragraph 7 above and footnote 2). Evidently, these

\(^4\) See also the Explanatory Notes to the new Rule 23e EPC by the EPO (CA/7/99 of 04.05.1999).
compounds comprise genetic information, but basically they should be considered as physical entities (chemical compounds) performing a function. However, whether an EST or SNP or genomic DNA is a patentable invention, is dependent on the fact whether they comply with all standard patentability requirements set in ROW 1995 and EPC. The mere fact that an EST, SNP or genomic DNA is isolated from the human body or from nature does not make it yet a patentable invention (see Directive Article 5.3 and new Rule 23e EPC). It fully depends on the technical disclosure in relation to these DNA sequences disclosure (such as sequences, isolation and function) whether these DNA sequences relate to a patentable invention.

6 Novelty

Question 3.4(a)

"Do EST's, SNP's or genomes form part of the state of the art in relation to full length gene sequences?"

16. The Dutch working group is of the opinion that EST's, SNP's, genomes and genomic DNA are to be considered as chemical compounds. Hence, the sequence and use of these DNA molecules form state of the art when their sequence and use became publically available at a relevant date. Accordingly, they form state of the art for later found longer and full lengths gene sequences. Although EST's, SNP's, genomes and genomic DNA form state of the art, this does not necessary mean that longer and full length gene sequences are no longer novel.

Question 3.4(b)

"If it is possible to patent an EST, SNP, should a later, longer gene sequence including that EST or SNP nevertheless be regarded as novel?"

17. According to Article 4(1) ROW 1995 and Article 54(2) EPC an invention is to be considered novel if it does not yet form state of the art. When deciding novelty of a gene sequence over EST or SNP it is to be decided, whether this gene sequence is different from the EST and SNP in sequence. Because the gene sequence is larger in gene sequence length this means, according to the Dutch working group, that the longer gene sequence is novel over the respective EST or SNP. However, this does not yet necessarily mean that this longer or full length gene sequence is inventive over the EST or SNP.

7 Obviousness

Question 3.5(a)

"What standard of obviousness should apply to inventions concerning EST's, SNP's and genomes?"

18. The Dutch working group is of the opinion that for EST's, SNP's, genomes (but also for genomic DNA) the traditional requirements and levels for patentability should apply. Accordingly, it is to be decided following the problem solution approach, whether the provision of an EST, SNP, genomic DNA or genome solved a particular
problem and whether the solution to this problem by the provision of the EST, SNP, genomic DNA or genome was inventive or obvious for the skilled person in view of the state of the art.

19. In this respect it is noted that nowadays it is seldomly difficult to synthesize or construct a DNA sequence. Under such circumstances obviousness is decided on the basis of the problem solved by the provided DNA sequence. This solved problem is linked to the function performed by the DNA sequence. Hence, the nature and character of this function generally will be the important criterium for determining inventiveness/obviousness.

**Question 3.5(b)**

"What particular difficulties do courts and patent examiners face in assessing inventive step?"

20. The Dutch working group is not familiar with any argument why the application of the problem solution approach in relation to EST's, SNP's, genomic DNA and genomes is different or more difficult from the application of this approach in relation to chemical compounds in general.

21. Furthermore, the decisions rendered by the Netherlands Patent Courts and by BIE and EPO show that they are adequately skilled in applying the problem solution approach in the assessment of an inventive step in relation to biotechnological inventions.

8 **Sufficiency**

**Question 3.6**

"What should be the sufficiency requirements for patents for EST's, SNP's and genomic DNA?"

22. When adapting the approach that EST's, SNP's, genomic DNA, and also genomes should be considered as chemical compounds, it follows that the sufficiency requirement is met when a patent specification in a manner sufficiently clear and complete enables a skilled person is able to carry out the invention. This means in relation to EST's, SNP's, genomic DNA, and genomes that the skilled person is able to synthesize these compounds, to obtain them from an identified gene bank or from an identified biological deposit. When the patent claim covers the gene in other related species, then the specification should comprise sufficient directives such that the skilled person, without undue burden is able to obtain the gene in the other species.

23. Effectively, the specification of the patent should be such that the skilled person is able to obtain substantially all DNA sequences that are covered by the patent claim.

24. Again the same requirements apply as for any other type of (chemical compound) invention.
9 Documenting DNA inventions

Question 3.7

"Are there, and should there be special provisions for the written description or claims (eg considering unity of invention) of EST's, SNP's and genomes?"

25. ROW 1995 (Article 11q and Rule 27a EPC) comprise special provisions in relation to listings of nucleotide sequences.

26. However, the written description and claims should be drafted such that the EST's, SNP's, genomic DNA and genomes are adequately disclosed, not only in relation to their obtainment but also in relation to their intended use or function. In other words, it should be disclosed which problem is solved by the provision of the EST's, SNP's, genomic DNA and genomes.

27. The Netherlands working group emphasizes that the standard requirement for unity of invention should be taken into account and strictly applied. This means that for the EST's, SNP's, genomic DNA and genomes it should be disclosed in the description which of their elements correlate with the disclosed inventive concept.

10 Scope of protection

Question 3.8(a)

"Should patent claims for EST's, SNP's and genomic DNA afford the same protection as other patent claims?"

28. When patent claims for EST's, SNP's, genomic DNA and genomes have been granted taking into account the standard requirements for patentability, then there is no basis to afford these type of patent claims, a patent protection different (more limited) for patent claims relating to other types of inventions. Obviously, the scope of protection should be in a justifiable balance with the contribution to the art of the patented invention.

29. It goes without saying, that the existing exceptions to patent infringement like private use and scientific research are equally applicable. In addition, the Dutch working group draws the attention to the availability of compulsory licensing on the basis of general interest according to a provision within Article 57 ROW 1995 when existing patent rights and attitude of the patentee unjustifiably would harm the general interest, such as making impossible or suboptimal medical treatments, therapy and diagnosis. Furthermore, Article 12(1) of the Directive comprises provisions for compulsory licencing on the basis of granted plant breeders rights.

30. Finally, it is noted that if patent rights are granted for EST's, SNP's, genomic DNA or genomes, which are not exploited (within the European community), that there is a possibility for obtaining a compulsory licence (Article 57(2) ROW 1995).
Résumé

1. Aux Pays-Bas, la structure juridique prévue pour les inventions biotechnologiques, EST, SNP, ADN génomique et génomes compris, est très semblable à la structure juridique définie par la Convention du Brevet Européen (CBE) et par la directive 98/44/CE sur la Protection juridique des inventions biotechnologiques.

2. L'EST, le SNP, l'ADN génomique et les génomes sont des séquences nucléotides. Ces séquences sont donc considérées comme des composantes chimiques soumises aux mêmes exigences standard d'octroi de brevet.

3. Ceci signifie, dans la structure juridique donnée pour ces séquences que:
   a) l'octroi de brevet en général n'est pas contraire aux bonnes moeurs;
   b) l'Office Européen des Brevets (OEB) est l'institution compétente et dispose de suffisamment de ressources pour examiner si soit la publication soit l'utilisation de ces séquences sont contraires aux bonnes moeurs;
   c) lorsque ces séquences peuvent être créées et utilisées, elles satisfont aux exigences d'utilité ou d'application industrielle;
   d) ces séquences, tout comme les composantes chimiques, peuvent être considérées comme une invention;
   e) la nouveauté de ces séquences est déterminée au regard d'autres séquences (identiques) précédentes représentant l'état de la technique;
   f) l'évidence est déterminée en considérant le problème comme résolu par la fourniture de ces séquences; les Tribunaux néerlandais des brevets, l'Office des brevets et l'OEB ne rencontrent pas de difficultés particulières lors de l'étape d'évaluation de l'évidence/du caractère inventif;
   g) les brevets pour ces séquences satisfont aux exigences de suffisance si l'information contenue dans le brevet permet aux personnes expérimentées d'obtenir ladite séquence par synthèse ou à partir d'un dépôt identifié;
   h) l'invention est suffisamment documentée si la description dudit brevet fournit une information adéquate pour l'obtention et pour l'usage prévu de la fonction de ladite séquence;
   i) l'échelle de protection des brevets pour ces séquences doit être confrontée à la contribution apportée à l'état de la technique; il existe des exceptions à la violation du droit de brevet (usage privé et recherche scientifique) et des clauses de licence obligatoire (du fait de la dépendance, du non usage et des droits accordés aux sélectionneurs).

Zusammenfassung

1. Der Rahmen der niederländischen Gesetzgebung über biotechnologische Entwicklungen, einschliesslich ESTs, SNPs, genomisches DNA und Genome, ähnelt im Grossen und Ganzen dem Rechtsrahmen, der vom Europäischen Patentübereinkommen (EPÜ) und der Richtlinie 98/44/EG über den "Rechtlichen Schutz biotechnologischer Erfindungen" vorgegeben wird.
2. ESTs, SNPs, genomisch DNA und Genome sind nukleotide Sequenzen. Diese Folgen gelten als chemische Zusammensetzungen, die denselben als Standard geltenden Patentierbarkeitskriterien unterliegen.

3. Innerhalb des gegebenen rechtlichen Rahmens bedeutet das für diese Sequenzen:

a) die **Patentierbarkeit** verstösst im allgemeinen nicht gegen die guten Sitten,

b) das Europäische Patentamt (EPA) ist das zuständige Institut und hat ausreichende Mittel zur Prüfung der Frage, ob die Offenbarung oder Benutzung dieser Sequenzen gegen die guten Sitten verstösst,

c) werden diese Sequenzen hergestellt und benutzt, so entsprechen sie allen Kriterien der **gewerblichen und industriellen Anwendbarkeit**, 

d) wie chemische Zusammensetzungen können diese Sequenzen als Erfindung gelten,

e) die **Neuheit** dieser Sequenzen wird in Bezug auf andere, frühere (identische) Sorten von Sequenzen bestimmt,

f) zur Bestimmung von **Naheliegendheit** wird das von den Ansprüchen der Sequenzen gelöste Problem erwogen. Die niederländischen Patentgerichte, das Niederländische Patentamt und das EPA haben keine besonderen Schwierigkeiten bei der Bewertung der Begriffe naheliegend und erfinderische Tätigkeit,

g) Patente für diese Sequenzen entsprechen dem Kriterium der **Ausführbarkeit**, falls dem Fachmann durch die Offenbarung des Patents ermöglicht wird, die Sequenzen durch Synthese oder von einem identifizierten Depot zu erhalten,

h) die Erfindung wurde ausreichend **beschrieben**, falls die Patentbeschreibung eine ausreichende Offenbarung für den Erhalt und die beabsichtigte Verwendung oder Wirkung der Sequenzen enthält, und

i) der **Schutzbereich** des Patents für diese Sequenzen ist in Bezug auf den offenbarten Beitrag zu der Sorte zu erwägen. Es gibt Ausnahmen von Patentverletzung (private Benutzung und wissenschaftliche Forschung) und Erfordernisse für obligatorische Lizenzierung (je nach Abhängigkeiten, Nicht-Benutzung und Pflanzenzüchttern gewährten Rechten).