

**PRE-GRANT PATENT OPINIONS IN
VIETNAM AND THEIR ROLE IN ACCESS
TO MEDICINES: A BRIEF PRACTICAL
GUIDE**

TAHIR AMIN

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I. Introduction

The difficult relationship between patents and access to medicines has been well documented.¹ This relationship was made more problematic after the introduction of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and the need for Members to implement minimum requirements for the patents on medicines. Much of the debate to date has focused on the flexibilities available to developing countries within TRIPS to ensure continued access to affordable medicines. These include Members utilising compulsory licensing mechanisms and adopting strict standards of patentability in order to prevent the practice of ‘evergreening’ within the pharmaceutical industry.²

One of the flexibilities available within TRIPS that has received less attention in the debate is the ability of Member States to implement mechanisms that allow third parties, such as members of the public, the right to file observations or oppositions at a Members national patent office against the granting of non-meritorious patents. This is partly due to the fact that many countries already have such mechanisms in some form in their patent laws. However, the lack of attention is also largely because of the technical nature of patents and the lack of awareness of such procedures.³ In addition, those who are aware of such procedures may be reluctant to utilise them given the narrow scope of intervention they often offer. As a result, these observation/pre-grant opposition procedures are rarely used.

Nevertheless, as will be discussed in Appendix II, recent events in India such as the well-publicised case concerning a patent application for the anti-cancer drug Gleevec (or Glivec), show how a pre-grant observation/opposition procedure can ensure continued affordable access to essential medicines. Equally as important, such a mechanism can ensure that examiners in patent offices who may be overburdened by a high number of applications or do not have the required expertise in a particular

¹ See for example, the Report of the Commission on Intellectual Property Rights, *Innovation and Public Health, Public Health Innovation and Intellectual Property Rights*, (April, 2006) at <http://www.who.int/intellectualproperty/documents/thereport/CIPHRReport23032006.pdf> and the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Rights*, (September 2002) at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf

² “Evergreening’ refers to the strategy adopted by patentees who seek to extend their period of patent protection by applying for secondary patents over related or derivative technologies. At first blush, the idea of evergreening seems an anathema to central tenets of the patent system, which provide protection for a limited term to ‘novel’ inventions. Accordingly, the practice of evergreening has been criticised as effectively enabling protection beyond the initial term despite only trivial changes to the invention itself.” Robert Chalmers *“Evergreen or Deciduous? Australian Trends in Relation to the ‘Evergreening’ of Patents”* 30 *Melb. U. L. Rev.* 29 (2006).

³ Argentina, Brazil, India, Indonesia, Pakistan Philippines and Thailand are some of the many countries that provide for a pre-grant observation or opposition mechanism. Amongst the developed countries, the European Patent Office and the United Kingdom provide for a pre-grant observation procedure (see Appendix I for an example of a UK Patent Office decision based on pre-grant observations by third parties). The United States offers members of the public the ability to file protest notices with the examiner against patent applications, see 37 *CFR 1.291, Chapter 1900* of the US Patent Manual for Examination. It should be noted, however, that many developing countries are being pressured through bilateral and free trade agreements to remove effective pre-grant observation and opposition mechanisms.

area, can benefit from third party observations/oppositions to ensure that a strong patent system is created.⁴

In light of the important role that pre-grant observation/oppositions can play in ensuring only quality of patents are granted and access to medicines are not unnecessarily blocked, the purpose of this paper is to provide a brief review and practical guide to utilising the pre-grant opinion mechanism that exists under Vietnam's patent laws. Part II of this paper will briefly analyse the scope of the provision available to third parties to file written opinions. Linked to this, the section will also provide a brief overview of how the law defines what an invention is, which will be relevant to anyone wanting to file an opinion. Part III will provide a basic introduction on how to find patents for particular medicines and understanding the essential features of a patent specification. Part IV provides a basic introduction on how to gather prior art and evidence for the purpose of supporting pre-grant opinions.

It should be noted that this is only a preliminary guide. A deeper understanding of patent law and the subject matter in question is required before embarking on filing written opinions to challenge patent applications. However, it is hoped that it will prove a useful starting point for generating interest in exploring the use of filing pre-grant opinions in Vietnam in order to create a stronger patent system.

⁴ There has been considerable debate recently in the United States over the quality of patents being issued and the burden put on examiners, including the short time they have to review applications (estimated to be only 20 hours on average). See <http://www.informationweek.com/industries/showArticle.jhtml?articleID=180204145&pgno=1&queryText=>

II. Pre-Grant Opinions in Vietnam and Related Provisions

A. Pre-Grant Opinions

The key provisions of Vietnam's Patent Laws can be found in Part III, Chapter VII of the Intellectual Property Law (IPL), Law No. 50/2005/QH11 under the heading Industrial Property Rights.⁵

On review of the IPL it is clear from Article 112 that the law provides third parties with the opportunity to present opinions to the State administrative authority (otherwise known as the National Office of Intellectual Property ('NOIP')) on the granting or refusal of a protection title to industrial property rights.⁶ Article 112 reads:

Article 112 - Third parties' opinions on the grant of Protection Titles

As from the date an industrial property registration application is published in the Industrial Property Official Gazette until prior to the date of decision on the grant of a Protection Title, any third party shall have the right to present opinions to the State administrative authority of industrial property rights in relation to the grant or refusal of a Protection Title in respect of the application. Such opinions must be given in written form and be accompanied by materials or must specify the source of information used for proving.

Article 117(4) - *Where there is a protest made against the intention to grant a protection title, the relevant industrial property registration application shall be re-examined with regard to the matters being protested against.*

In order to understand the scope of the rights that Article 112 provides for the purpose of challenging patents, the key points are:

- a) That *any third party* shall have the right to present opinions in relation to the grant or refusal of a protection title for an application.

The key words to note are *any* and *third party*. This wording leaves no ambiguity that any individual, company or other entity can present an opinion to the NOIP on whether an application for a patent should be allowed.

⁵ The law as analysed in this paper is based on an English translation provided to the author. The author takes no responsibility for any errors in the translation.

⁶ For the purpose of understanding the definitions and terminologies given to particular terms in the law, the reader is directed to Article 1 of the IPL. Article 1(4) of the IPL defines inventions as 'industrial property rights' and not the commonly used term patents. This should not confuse the reader, as it is clear that industrial property rights are akin to patents and inventions for the purpose of the law. Article 1(25) defines 'Protection title' as a document granted by the NOIP to an organisation or individual for its invention. This will essentially be an official certificate confirming the invention and the rights of the party that go along with it. For the remainder of this paper, the term patent will be used when referring to industrial property rights and protection titles.

- b) Any third party shall have the right to present opinion to the *grant or refusal* of a patent.

This provides an interesting possibility as the provision not only allows any third party to provide an opinion contesting an application for a patent, but also equally allows opinions on whether the patent should be granted. Note the use of the word *or* between the words grant or refusal. It is likely that for this purpose, the applicant will not be permitted to present an opinion under Article 112, as he/she would not classify as any third party. The provision is clear that it is only applicable to other parties. This is probably to prevent the applicant taking advantage and abusing the provision. Indeed there is a separate procedure that an applicant must follow in order to overcome any objections raised against an application.⁷

- c) The opinion against the granting of a patent application must be made in *writing* accompanied by *materials*. It is clear that any opinion must be presented in written form. It appears that the law does not require any particular written form, but it is always useful to ask the NOIP to see whether they have issued any practice notes on this point. By materials, it is understood the law is referring to any evidence supporting the written opinion. It is important to note that the source of such evidence should also be provided. This will usually include prior art, such as an earlier patent covering the same or similar invention, a science publication describing the invention claimed or other expert evidence from someone in the industry showing that the invention would have been obvious to a person in the that field.
- d) Article 112 does not restrict the grounds upon which an opinion can be based. Therefore, it appears that third parties can invoke any form of evidence to show that an invention should not be granted. However, it is likely that any evidence will have to follow the criteria that the claimed invention does not meet the test of novelty, inventive step, industrial applicability and sufficient disclosure of the invention. These criteria are discussed briefly below.
- e) The period within which to file an opinion starts once the application in question is published in the Official Gazette of the NOIP and runs until the patent is granted.⁸ While there is no fixed time period within which the opinion should be filed, it is always advisable not to delay filing as once a patent is granted the opportunity to file a written opinion will be missed and cannot be re-instated.⁹ Therefore, it is important for any person interested in submitting an opinion to be observing the publication of applications in the Official Gazette, though as will be explained in Part III it is possible to anticipate if applications have been made in Vietnam through conducting international patent searches.

⁷ Article 109 provides for the examination procedure that an applicant must go through in order to be granted a patent. This includes dealing with any objections raised by the NOIP.

⁸ Article 110 provides that publication of an application will take place on the nineteenth month after the filing date of the application of priority date claimed, or earlier if requested by the applicant.

⁹ Article 119 provides that examination of an application should take place within 12 months from the date of application if a request for examination is made by the applicant before publication, or 12 months from the date of request for examination if made after publication.

In summary, the scope of Article 112 is unlimited to the extent any third party can base an opinion on any ground which may show that the invention is not patentable. This makes for a useful pre-grant opposition mechanism, as it does not restrict a potential opponent. That said, the impact of such opinions would be determined by how the NOIP interprets what an invention is and this is what we turn to next.

B. Defining an Invention

Anyone wishing to file an opinion under Article 112 needs to be versed in Vietnam's standards for defining an invention. The current practice adopted by the NOIP and any related case law is outside the scope of review of this paper. However, an analysis of the relevant provisions show that Vietnam has adopted the standard patentability criteria based on novelty, inventive step and industrial application, alongside subject matter that is excluded as being patentable.

Article 1(12) defines an invention as a *technical solution* to resolve a specific problem by utilising the laws of nature. The use of the phrase 'to resolve a specific problem' has the risk of being interpreted broadly so as to encourage the practice of evergreening. This is because the term 'specific problem' could be argued to permit nominal and minor modifications to existing substances that may not in any way improve the actual product, but are useful in terms of solving a specific problem such as manufacturing. In light of this definition, the importance of filing pre-grant written opinions cannot be understated as they could help the NOIP in assessing what really should be considered a specific problem for the purpose of an invention rather than how the applicant may want to define the term.

Article 59, excludes from the following from being inventions:

- Discoveries, scientific theories; mathematical methods;
- Schemes, plans, rules or methods for performing mental acts, training domestic animals, playing games, doing business; computer programs;
- Presentations of information;
- Solutions of aesthetic characteristics only;
- Plant varieties, animal varieties;
- Processes of essentially biological nature for the production of plants and animals other than microbiological processes;
- Disease prevention, diagnostic and treatment methods for human or animals.”

The only exception listed in Article 59 that may be relevant when filing opinions against pharmaceutical applications is that relating to treatment methods for humans or animals. Very often patent applications for pharmaceutical products will claim treatment methods. Under Art 59, such claims would not be patentable. An example of a claim for a method of treatment may look like this:

line	80 9-(2-hydroxypropyl)adenine solution.
vs.	8. A composition comprising an (R,S)-PMPA solution at a pH of about 2.7–3.5 wherein the solution has less than about 0.1 g/mL (R,S)-PMPA and wherein about 90–94% of the PMPA is in the (R) configuration.
1	35 9. A method comprising orally administering to a patient infected with virus or at risk to viral infection a therapeutically effective amount of a composition of claim 1.
	10. A method comprising contacting bis(DOC)PMPA with fumaric acid.
40	11. The method of claim 10 wherein the fumaric acid is dissolved in 2-propanol.

US Patent No. 5935946

Other than claims made for therapeutic treatment methods for humans, the exceptions to what a pharmaceutical invention are limited. As will be discussed in Part IV below, India has adopted a very stringent definition within its exceptions to patentability to ensure against the practice of evergreening.

The test for what can be an invention is set out in Article 58. Vietnam has adopted the standard three step test for patentability as set out in TRIPS – that the applicant show that the claimed invention is novel (new), includes inventive step and is capable of industrial application.

Articles 60 and 61 define what is novelty and inventive step. The novelty test is an absolute test, in that public disclosure of an invention before its priority date or filing date anywhere in the world is capable of making the claimed invention invalid. Therefore, publications, prior use or common general knowledge in the relevant field can all be used to attack the novelty of a patent application. The novelty test can be applied in different ways. Some countries require an exact disclosure of the claimed invention before novelty of an invention can be attacked. Other countries may allow general disclosures as breaking novelty. For example, an earlier patent application that discloses a number of potential salts for a compound, but which does not actually claim or describe them, could still be considered to attack the novelty of an application.

Article 61, which describes the test for inventive step, essentially requires that in light of the existing literature, publications, knowledge or other disclosures, the claimed invention could not be easily created by an ordinary person in that field. Therefore, this requires anyone filing an opinion to show that the inventive step claimed by an applicant would have been obvious to a skilled person in the pharmaceutical industry. Unless the publication and general knowledge available clearly shows that the invention claimed was obvious, this requirement may require evidence from skilled technicians in the industry to demonstrate this point.

The standard for industrial application is “if it is possible to carry out massive production or manufacture of the product or repeated application of the process that is

the subject matter of the invention and *achieve stable results.*” On a plain reading, if an invention is capable of being produced in a large scale without any variation in the end result, it will meet this requirement.¹⁰

¹⁰ It is possible, for example, to argue that the industrial application standard require applicants to show how useful a product can be. For example, the U.S. Court of Federal Appeals heard a case, in *re Brana*, wherein the United States Patent and Trade Mark Office (‘USPTO’) had requested a patent applicant for evidence, clinical trial data, that the product was useful in humans under its equivalent test for industrial application, known as the utility test. Although ultimately the Court held that pre-clinical data was sufficient to meet patentability standards, this case serves as a useful reminder that the requirement for what is industrially applicable can be stretched to include its usefulness.

III. Finding Patents and Understanding Patent Applications

A. Finding a Patent for a Pharmaceutical Product

For a person who is unfamiliar with patents, is not in the pharmaceutical industry and does not have access to subscription based commercial databases or the relevant technical knowledge, finding the patent that matches a particular product can be a daunting task. Fortunately, there are free resources available on the internet that can help to identify or at least narrow the search for patents that have been filed for particular pharmaceutical products. While these resources relate to US patents for products, it is likely that these patents will be the applications from which the corresponding Vietnam application claims priority. Even if priority is not claimed from a US application, obtaining such a corresponding patent specification can reduce the search time when reviewing the Official Gazette for publications for the same application. This is because it should be possible to match the abstracts and the title of the invention.¹¹

Useful Databases – There are a number of resources on the internet that match patents with actual products. This section focuses on those that can be accessed freely.

The US Food and Drug Administration (FDA) provides an easy to use search facility for the purpose of identifying FDA approved drugs for marketing in the US and their related unexpired patents. This facility is known as the *Approved Drug Products with Therapeutic Equivalence Evaluations* or more commonly the *Orange Book*.¹² While the Orange Book lists the relevant US patent numbers for each product, it does not provide a direct link to the patent specification.¹³ A more user friendly and complete resource is *Minesoft – FDA Orange Book*.¹⁴ Minesoft not only links into the data provided in FDA Orange Book, but provides direct links to the United States Patent and Trade Mark Office (USPTO) so users do not have to conduct a separate search for the patent. For the purpose of providing working examples of the various search options and information available from the Orange Book, the Minesoft search facility is referred to.

As Fig 1 shows below, the home page for Minesoft provides four search options, ‘Patents’, ‘Exclusivity’, ‘Search’ and ‘Browse’. The circled link ‘Search’ is the most direct of the search options. The search parameters under ‘Patents’ or ‘Exclusivity’ are based on ‘Company Name’ and do not provide direct hits for a particular product.¹⁵

¹¹ It is not always the case that the titles for the same corresponding application will be the same.

¹² See <http://www.fda.gov/cder/ob/default.htm>

¹³ The user is required to take note of the patent number and then access the USPTO website and search for the relevant patent there. See <http://www.uspto.gov/> and <http://www.uspto.gov/patft/index.html>

¹⁴ See <http://fda.minesoft.net/info.asp>. However, it should be noted that the Orange Book may not include all related patents and may have errors. Another useful site that links patent information to approved products in the Orange Book is <http://www.bigpatents.com/browse/orangebook>. Bigpatents offers a free basic search service as well as premium products, which require subscription.

¹⁵ For example, a search using the option ‘Patents’ and the company name ‘Glaxosmithkline’ will reveal 344 hits.



Fig 1. Front page of Minesoft and available search options

Under the option ‘Search’, the user is offered the following further options to narrow the search (see Fig 2):

- (a) Search by Active Ingredient’ – this is the generic chemical name that the product in question contains, e.g. Adefovir, Ritonavir, Tenofovir, Abacavir.
- (b) ‘Search by Proprietary Name – this is the brand name under which a product is e.g. Hepsera ®, Norvir ®, Viread®, Ziagen®; and/or

The results of the search will display the product Adefovir/ Hepsera® and the application number for marketing approval in the US (see Fig x).



Fig 2. Search fields available under the option ‘Search’

Application number	Proprietary name	Active ingredient	Applicant
021449	HEPSERA	ADEFOVIR DIPIVOXIL	GILEAD

Fig 3. Result of search for ‘Adefovir’ or ‘Hepsera’

By clicking on the ‘Application number’, as shown in Fig 3, the user is directed to a new page which lists the various patents that have been filed in the US relating to the product Adefovir/Hepsera®, see Fig 4. The link ‘view’ then directs the user to the USPTO and the relevant patent specification (see Fig 5).¹⁶ As is the case with most products, there will usually be more than one related patent. It is at this point that a review of the listed patents will have to be made in order to identify the particular patent that is of interest.

FDA Application Number: 021449 (001)	
Proprietary Name:	HEPSERA
Active Ingredient:	ADEFOVIR DIPIVOXIL
Applicant:	GILEAD
Route / Dosage form:	TABLET; ORAL
Strength:	10MG
Prescription / OTC:	Prescription
Date of approval:	Friday, September 20, 2002
Reference listed drug:	Yes
Patent number	US4724233 view legal (expiry: 4/21/2006)
Patent number	US4808716 view legal (expiry: 4/25/2006)
Patent number	US5663159 view legal (expiry: 9/2/2014)
Patent number	US6451340 view legal (expiry: 7/23/2018)
Exclusivity	NCE (expiry: 9/20/2007)

Fig 4. US Patents for ‘Adefovir/Hepsera®’

¹⁶ The specification provided from the USPTO website will not show the diagrams of the compounds or formulas. For free downloadable PDF versions of US, European Patent Office, Japanese and International patents which are easier and clearer to read visit www.patentmatic.com or www.freepatentsonline.com

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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(1 of 1)

United States Patent **6,451,340**
Arimilli , et al. **September 17, 2002**

Nucleotide analog compositions

Abstract

The invention provides crystalline forms of adefovir dipivoxil and methods to prepare the crystals. The compositions and methods of the present invention have desirable properties for large scale synthesis of crystalline adefovir dipivoxil or for its formulation into therapeutic dosages. Invention compositions include an anhydrous crystal form of adefovir dipivoxil.

Inventors: **Arimilli; Murty N.** (Fremont, CA), **Kelly; Daphne E.** (San Francisco, CA), **Lee; Thomas T. K.** (Redwood City, CA), **Manes; Lawrence V.** (Moss Beach, CA), **Munger, Jr.; John D.** (Alviso, CA), **Prisbe; Ernest J.** (Los Altos, CA), **Schultze; Lisa M.** (San Carlos, CA)
Assignee: **Gilead Sciences, Inc.** (Foster City, CA)
Appl. No.: **09/950,031**

Fig 5. US Patent No. 6451,340

B. Has an Application for a Patent Been Filed in Vietnam?

The next step will be to see whether a particular application has been filed in Vietnam. The obvious starting point will be to check with the NOIP and regularly monitor the Official Gazette. The NOIP does offer a search facility on its website, but it is not clear whether the database is up to date.¹⁷

In the event it is difficult to retrieve the information from the NOIP or its website, an alternative way of determining whether a patent has been filed in Vietnam is to conduct an international patent search. This can be done for free through the website Espacenet®, which is a search facility provided by the European Patent Office.¹⁸

Espacenet, provides various search options to the user. These include an ‘Advance Search’, ‘Number Search’. ‘Quick Search’. The ‘number Search’ option is the quickest method for searching, in particular if the steps discussed above have already been taken. By opting for a ‘worldwide search’ simply insert the US patent number retrieved through Minesoft in to the box marked number (see Fig 6 below).

¹⁷ <http://www.noip.gov.vn/>

¹⁸ As many countries do not still provide patent information in an electronic form, Espacenet will not contain information or countries. See http://ep.espacenet.com/search97cgi/s97_cgi.exe?Action=FormGen&Template=ep/EN/home.hts

Number Search

1. Database

Select the patent database in which you wish to search:

Database:

2. Enter number

Enter either an application, accession, publication or priority number with or without country prefix

Number:

Fig 6. Number search – Espacenet

On clicking the ‘search’ button, the page shown in Fig 7 will appear. This displays that the US Patent has been found. By clicking on the link ‘Nucleotide analog compositions’, the user is directed to a page displaying details of the application (see Fig 8) and a link that allows the user to view the ‘family of patents’ (otherwise called ‘View INPAPDOC patent family’) relating to the patent’. The ‘family of patents’ then lists the corresponding patents that have been filed in other countries, where information is available and link to each (see Fig 9).

RESULT LIST
 1 result found in the Worldwide database for:
US6451340 (priority or application number or publication number)
 (Results are sorted by date of upload in database)

1 **Nucleotide analog compositions**

Inventor: ARIMILLI MURTY N (US); KELLY DAPHNE E (US); **Applicant:** GILEAD SCIENCES INC (US)
 (+5)

EC: A61K31/675; C07F9/6561E **IPC:** A61K31/675; C07F9/6561; A61K31/675

Publication info: US2002045599 - 2002-04-18

Data supplied from the **esp@cenet** database - Worldwid

Fig 7. Search result

Nucleotide analog compositions

Publication number: US2002045599 Also published as:  US6451340 (B1)

Publication date: 2002-04-18

Inventor: ARIMILLI MURTY N (US); KELLY DAPHNE E (US); LEE THOMAS T K (US); MANES LAWRENCE V (US); MUNGER JOHN D (US); PRISBE ERNEST J (US); SCHULTZE LISA M (US)

Applicant: GILEAD SCIENCES INC (US)

Classification:

- international: **A61K31/675; C07F9/6561; A61K31/675; C07F9/00;** (IPC1-7): A61K31/675; C07F9/6512
- european: A61K31/675; C07F9/6561E

Application number: US20010950031 20010910

Priority number(s): US20010950031 20010910; US19980121163 19980723; US19970053771P 19970725

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Abstract of US2002045599

The invention provides crystalline forms of adefovir dipivoxil and methods to prepare the crystals. The compositions and methods of the present invention have desirable properties for large scale synthesis of crystalline adefovir dipivoxil or for its formulation into therapeutic dosages. Invention compositions include an anhydrous crystal form of adefovir dipivoxil.

Fig 8. – Details of US patent

Family list [Back to US2002045599](#)

59 family members for:
US2002045599
Derived from 50 applications.

- 41 NUCLEOTIDE ANALOG COMPOSITIONS**
Publication info: **SI996430T T1** - 2003-04-30
- 42 Process for preparing Adefovir Dipivoxil**
Publication info: **SI1256584T T1** - 2005-02-28
- 43 Process for preparing 9-(2-(diethylphosphonomethoxy)ethyl)-adenine**
Publication info: **SI1256585T T1** - 2005-02-28
- 44 NUCLEOTIDE ANALOG COMPOSITIONS**
Publication info: **TR200000224T T2** - 2000-07-21
- 45 Nükleotid analog kompozisyonlar**
Publication info: **TR200200117T T2** - 2002-06-21
- 46 NUCLEOTIDE ANALOG COMPOSITIONS**
Publication info: **TR200200137T T2** - 2002-09-23
- 47 Crystalline adefovir dipivoxil, pharmaceutical compositions comprising the same and methods for preparing them**
Publication info: **TW584635B B** - 2004-04-21
- 48 Nucleotide analog compositions**
Publication info: **US6451340 B1** - 2002-09-17
US2002045599 A1 - 2002-04-18
- 49 NUCLEOTIDE ANALOG COMPOSITIONS**
Publication info: **WO9904774 A2** - 1999-02-04
WO9904774 A3 - 1999-04-15
- 50 Nucleotide analog composition**
Publication info: **ZA9806614 A** - 1999-01-27

Data supplied from the [esp@cenet](#) database - Worldwide

Fig 9. - Patent family list for US Patent No. 645130

If the letters ‘VN’ do not appear in the list, this means that either Espacenet does not have the information on Vietnam, an application may have been filed under the Patent Co-operation Treaty (otherwise called an International or PCT application) or that no application was filed at all.¹⁹ It is often the case that an applicant may have filed using the PCT application route. On the family list of patents, the initials ‘WO’ indicate a

¹⁹ The Patent Co-operation Treaty (‘PCT’) permits an applicant to file one single application that designates several countries.

PCT application, which is an abbreviation for WIPO (the World Intellectual Property Organisation). Therefore, by clicking on the link for ‘WO’ it will be possible to download the PCT application in order to establish whether Vietnam been designated by the applicant. Fig 10 provides an example.


PCT		WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau		
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)				
(51) International Patent Classification ⁶ : C07F 9/6561, A61K 31/675, C07F 9/6512		A1	(11) International Publication Number: WO 98/04569	
			(43) International Publication Date: 5 February 1998 (05.02.98)	
(21) International Application Number: PCT/US97/13244		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).		
(22) International Filing Date: 25 July 1997 (25.07.97)				
(30) Priority Data:				
08/686,838 26 July 1996 (26.07.96) US 60/022,708 26 July 1996 (26.07.96) US				
(71) Applicant: GILEAD SCIENCES, INC. [US/US]; 333 Lakeside Drive, Foster City, CA 94404 (US).				

Fig 10 – PCT Application and country designation

Despite all the above, it will still be necessary to check with the NOIP in order to locate any PCT applications and to know when they have been published in order that pre-grant opinions can be filed.

C. Understanding Patent Specifications

In order to be able to file a pre-grant opinion against an application, the relevant patent specification will need to be obtained from the NOIP. If the application filed in Vietnam is based on a PCT application, then it is possible to at least start reviewing that specification which can be obtained in the way described above.

Reviewing a patent specification for a pharmaceutical product can be a difficult process, given that it contains technical information that only an organic chemist or other person skilled in the art is likely to understand. However, through internet research and reading around a particular product, it is possible to gain enough knowledge to have a basic understanding so that at least any discussion or clarification sought from an organic chemist will have meaning.

Patent specifications are generally divided in to the following order:

- The first part includes the administrative information for patent offices, such as application number, priority date (if claimed), filing date, publication date, classification of the invention, the applicant and first inventor(s) details.²⁰

²⁰ Claiming priority is term used to describe a procedure where the applicant is entitled to base a later application on the first filing ever made for the invention in another convention country. This later

- The above information is then followed by the title of the invention and a short abstract explaining the invention.
- Following the abstract, the applicant will provide the background to the invention, which will list any prior publications that have discussed but not solved or explained how to solve the issues that the invention claims to have achieved.
- The specification then provides a detailed description of the invention and should explain clearly the method for explaining the invention, including working examples and tests of how the claims made were achieved.
- Finally, but most significantly, at the end of the specification are the claims of the invention. The claims define the scope of protection that the applicant is requesting be given for the invention. Anything that is not set out in the claims is disclaimed and cannot be granted protection. Like the specification the claims must not be ambiguous.

Examples of the above parts are shown in Figs 11- 14 below.


PCT		WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau							
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)									
<p>(51) International Patent Classification ⁶ :</p> <p>C07H 19/10, 19/20, A61K 31/70, C07F 9/6561, 9/6509, 9/6571, 9/6558, A61K 31/685, C07F 9/6564, 9/36, 9/40, 9/6512, 9/58, 9/09, 9/44, G01N 33 /53</p>	AI	<p>(11) International Publication Number: WO 95/07920</p> <p>(43) International Publication Date: 23 March 1995 (23.03.95)</p>							
<p>(21) International Application Number: PCT/US94/10539</p> <p>(22) International Filing Date: 16 September 1994 (16.09.94)</p> <p>(30) Priority Data:</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">08/123,483</td> <td style="width: 40%;">17 September 1993 (17.09.93)</td> <td style="width: 30%;">US</td> </tr> <tr> <td>08/193,341</td> <td>8 February 1994 (08.02.94)</td> <td>US</td> </tr> </table> <p>(71) Applicant (for all designated States except US): GILEAD SCIENCES, INC. [US/US]; 353 Lakeside Drive, Foster City, CA 94404 (US).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): BISCHOFBERGER, Norbert, W. [AT/US]; 105 Glasgow Lane, San Carlos, CA 94070 (US). JONES, Robert, J. [US/US]; 1020 Murchinson Drive, Millbrane, CA 94030 (US). ARMILLI, Murty, N. [IN/US]; 4789 Ridgewood Drive, Fremont, CA 94555 (US). LI, Kuei-Ying [US/US]; 4774 Canvasback Common, Fremont, CA 94555 (US). LOUIE, Michael, S. [US/US]; 1669 McKinley Street, San Mateo, CA 94403 (US). MCGEE, Lawrence, R. [US/US]; 1 Crater Lake Way, Pacifica, CA 94044 (US). PRISBE, Ernest, J. [US/US]; 1336 Richardson Avenue, Los Altos, CA 94024 (US). LEE, William, A.</p>	08/123,483	17 September 1993 (17.09.93)	US	08/193,341	8 February 1994 (08.02.94)	US	<p>[US/US]: 749 Anderson Drive, Los Altos, CA 94024 (US). CUNDY, Kenneth, C. [US/US]; 3802 Naughton Avenue, Belmont, CA 94002 (US).</p> <p>(74) Agents: MUENCHAU, Daryl, D. et al.; Gilead Sciences, Inc., 353 Lakeside Drive, Foster City, CA 94404 (US).</p> <p>(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>		
08/123,483	17 September 1993 (17.09.93)	US							
08/193,341	8 February 1994 (08.02.94)	US							

Fig 11 – The ‘administrative’ section of a patent specification, including priority data and the filing date. The numbers listed under the priority data are those of the first application from which priority is claimed. The publication date is the date the application was first published. The international classification data defines the category of the invention, such as ‘medical products for humans’.

filing has to be made within twelve months of the first application. A convention country is one that is a member of the Paris Convention or the World Trade Organisation.

(54) Title: NUCLEOTIDE ANALOGS

(57) Abstract

Nucleotide analogs characterized by the presence of an amide linked amino acid or an ester linked group which is bonded to the phosphorus atom of phosphonate nucleotide analogs are disclosed. The analogs comprise a phosphoamide or ester bond that is hydrolysed *in vivo* to yield a corresponding phosphonate nucleotide analog. Methods and intermediates for the synthesis and use are described.

Fig 12. – The Title and Abstract

NUCLEOTIDE ANALOGS

5

Background of the Invention

The present invention relates to novel nucleotide analog amidates and esters, their pharmaceutically acceptable acid addition salts, a process for their production, and to their use. The nucleotides of the present invention exhibit antitumor/antineoplastic activity, a broad spectrum of antimicrobial activity and certain other desirable activities.

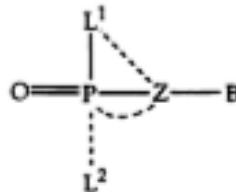
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Compounds related to the nucleotide analogs of the present invention may be found in: U.S. Patent Numbers 5,043,339, 5,108,994 and 5,166,198; EP 206 459; EP 253 412; EP 269 947; EP 270 885; EP 319 228; EP 343 133; EP 398 231; EP 404 296; EP 465 297; EP 468 119; EP 468 866; EP 479 640; EP 481 214; EP 494 370; EP 531 597; PCT/GB91/01171; PCT/US92/01020; PCT/US92/05208; WO 91/19721; Bronson et al, *Bioorg Medicinal Chem Lett* (1992) 2:685-690; Bronson et al, *J Med Chem* (1989) 32:1457-1463; Bronson et al, *Nucleotide Analogs as Antiviral Agents*, ACS Symposium Series 401, J.C. Martin, Ed., p. 72-87, American Chemical Society, Washington, DC (1989); Colla, et al, *J Med Chem* (1983) 26:602-604; Curley, et al, *Antiviral Res* (1990) 14:345-356; De Clercq, et al, *Nature* (1986) 323:464-467; Farrow, et al, *J Med Chem* (1990) 33:1400-1406; Farquhar, et al, *J Pharm Sci* (1983) 72:324-325; Freed, et al, *Biochem Pharmacol* (1989) 19:3193-3198; Freeman, et al, *J Med Chem* (1992) 35:3192-3196; Gabrielsen, B., et al, *Antiviral Res Suppl I* (1992) 17:149; Gumpert, et al, *Proc Natl Acad Sci* (1971) 2559-2563; Juodka, et al, *Coll Czech Chem Commun* (1974) 39:963-968; Kim, et al, *Bioorg Medicinal Chem Lett* (1992) 2:367-370; Kim, et al, *Tet Lett* (1992) 33:25-28; Kim, et al, *J Med Chem* (1990) 33:1207-1213; Kumar, et al, *J Med Chem* (1990) 33:2368-2375; McGuigan, et al, *Antiviral Chem Chemother* (1993) 4:97-101; McGuigan, et al, *Antiviral Res* (1991) 15:255-263; Rosenberg, et al, *Coll Czech Chem Commun* (1988) 53:2753-2777; Rosenberg, et al, *Coll Czech Chem Commun* (1988) 52:2792-2800;

Fig 13. – Background of the invention, including relevant prior patents and publications

What is claimed is:

1. A compound of the formula I

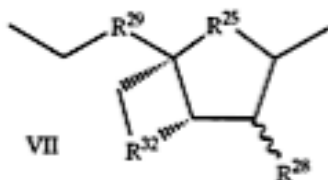
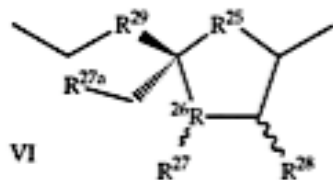
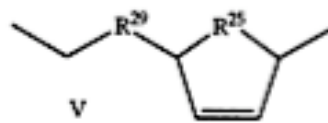
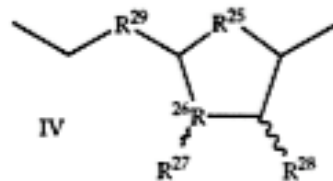


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or a physiologically acceptable salt thereof, wherein

L¹ and L² are independently an amino acid or polypeptide residue bonded to the phosphorus atom of the nucleotide analog amidate by an amidate bond, or an oxyester, thioester, a substituted or unsubstituted amine, or hydroxy, provided that one or both of L¹ and L² is an amino acid or polypeptide residue and any carboxyl group that is linked by less than about 5 atoms to the amidate N is esterified or amidated and the dotted lines represent facultative bonds;

10 Z is -CHR⁷-R¹¹-(CH₂)_{m1}-C⁸(R⁸)((CH₂)_{m2}(R⁹))-(CH₂)_{m3}-R¹⁰-(CH₂)_{m4}-, -Q-
15 C₆H₄-CH₂-, -CHR⁷-O-CHR⁷-O-CHR⁷-, -CHR⁷-(CHR¹³)_{m1}-CHR¹⁴-R¹⁰-,



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Fig 14. – The claims of a patent application. The claims will be numbered from one onwards. Claim number 1 will be the broadest and be the main claim, often called an ‘independent claim’. The following claims are often referred to as ‘dependent’ claims and are narrower in scope.

IV. Finding Prior Art and Evidence

Any pre-grant opinion against the granting of an application should be supported by evidence. Mere statements or hearsay that an invention is not novel or is obvious will not amount in a successful opposition. Aside from obtaining evidence from a skilled person in the field, significant research and analysis is usually required to obtain evidence that shows an application is not novel or would be obvious to someone skilled in the art. This section is not intended to provide comprehensive guidance on how to conduct prior art searches, but is simply an introduction to some starting points.

A useful first starting point is to examine what is known as the prosecution history of a corresponding application from another patent office. The European Patent Office provides such a facility called Epoline and which is also free to access.²¹ By registering on Epoline, users can access the file history of the examination of applications by the European Patent Office (EPO). The purpose of the exercise is not to follow the EPO's conclusions, but to obtain any insight into objections it may have raised, including any prior art cited, and how the applicant responded. Such insights can be invaluable as they may show how applicants have dropped or amended claims. It may also provide leads to other possible arguments that may have been missed by the examiner. Moreover, the file history can provide a useful starting point in finding prior publications that may have been referred to.

Another useful exercise is to review the corresponding US patent for the invention in question. Unlike other countries, applicants in the US must disclose all prior art that was known to the applicant at the time of filing, else risk the patent being invalidated. Therefore, US patents often include a more prior art citations than other country requirements. This may not only be useful for obtaining the background to the invention claimed, but also providing further directions to other relevant publications which the applicant may not have cited

Other useful resources are science journals, although many may require a subscription fee to review articles. By searching around the area of invention, one can obtain a number of publications that may suggest that the invention claimed may lack novelty and/or obviousness. Some useful resources include:

- Ingentaconnect
- Scifinder
- PubMed
- Sciencedirect
- Nature
- Delphion and Derwent

²¹ <http://www.epoline.org/portal/public>

Appendix I - Pre-grant Representations of Opposition in India

In 2005, India amended its Patent Act to permit patent protection on pharmaceutical products in order to comply with its obligations under TRIPS. This change could potentially have a severe impact on the continued production by Indian companies of affordable generic medicines for its own population and other developing countries.

In order to safeguard against India made two significant amendments to its patent law, but which are technically in compliance with the requirements of TRIPS.

The first of the two key amendments was to create a standard of patentability for pharmaceutical products aimed at curbing evergreening practices. Section 3d of the Patent Act states that the following will not be considered inventions:

“the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, *unless they differ significantly in properties with regard to efficacy.”*

The requirement that an applicant must show that a new form of a known pharmaceutical substance has an enhancement in efficacy has the potential, if applied correctly, to prevent a number of current drugs on the market being patented. More importantly, it sets a standard of patentability that could potentially create for true innovation and inventions.

The other key amendment was to maintain a procedure allowing for any person to file a representation of opposition and a hearing at the patent office with respect to the granting of a patent. There are eleven possible grounds under which a pre-grant representation procedure can be based, including the section 3d provision. This right, coupled with the definition above for what are not inventions, provides for suitable safeguards against non-meritorious patents.

Indeed, this was demonstrated in the well-documented case concerning Novartis’s application for the anti-cancer drug Gleevec (or Glivec), which was opposed by Indian companies and a local cancer patient group. The Patent Office in Chennai held that the drug was simply a new form of an old drug that had already been patented in 1993. Also as Novartis could not show that the invention applied for showed an increase in efficacy over the already known substance as required by the new section 3d, the application was refused.²²

²² The decision of the Chennai Patent Office has been appealed by Novartis.

Further evidence of how important a functional pre-grant opposition procedure can be is in the case of the oppositions filed by patient groups against the drug Viread® (Tenofovir Disoproxil Fumarate), a key first/second line ARV. Although a decision on the opposition has yet to be given, Gilead the applicant has on its own accord agreed voluntary licences with more than six Indian companies to manufacture the drug. Although not admitted by a Gilead, this unusual step by a company to offer to grant voluntary licences shows that using the opposition procedure can provide leverage in gaining affordable access to medicines where the patent application may not be patentable.²³

Since the introduction of the new pre-grant representation of opposition procedure, over one hundred and fifty oppositions have been filed out of a possible 36,000 published applications. These figures show that contrary to arguments put forward by some of the major pharmaceutical companies, the procedure is not being abused by companies and civil society. Instead, it is serving to ensure that non-meritorious patents are being weeded out in order to ensure access to affordable medicines through their continued production.

²³ Another example of the success of a pre-grant representation in India has been Glaxosmithkline's withdrawal of its application for Combivir® (Lamivudine and Zidovudine).

Appendix II

UK Patent Office Decision - In the Matter of Patent Application No. GB9522134.7 in the name of Colin Rooney (see attached)

PATENTS ACT 1977

IN THE MATTER OF

Patent Application No. GB 9522134.7

in the name of Colin Rooney

DECISION

1. The application in suit relates to animal husbandry sanitising compositions. Claim 1 defines such compositions as being in solid form and comprising an alkali metal peroxymonosulphate triple salt acting as a strongly oxidising source, sulphamic acid as an acid medium and chlorine acceptor, an alkali metal phosphate as sequestering agent, a surfactant and a chlorinated isocyanurate as an organic source of available chlorine. Claim 5 relates to a particular formulation which has become known as Virucidal Extra.

2. The application was filed in the name of Vincent Rooney on 30 October 1995 without a claim to priority. A deed of assignment dated 6 November 1998 subsequently transferred the application to Colin Rooney. The normal period for putting it in order for grant expired on 30 April 2000. However, the applicant has filed the necessary form and fee required under Rule 110(3) of the Patents Rules 1995 to extend that period by one month, as of right, so the final date for putting the application in order is now 30 May 2000. In spite of considerable correspondence between the examiner and the applicant there has not been agreement concerning, in particular, whether the invention as defined in claims 1 and 5 is novel as required by section 1(1)(a) of the Act. Since time for agreement was running out the applicant requested, in a letter dated 18 May 2000, that the matter be referred to a "senior officer" to be decided on the papers. It has fallen to me to make the decision.

3. Having studied all the papers it seems to me that this case presents some unusual features which I must address carefully in my decision. In view of the fact that I must give my

decision by the final date, 30 May 2000, I am aware that I will not have time to set out my reasons in detail so this decision will be brief and will be followed by a Statement of Reasons in due course.

4. Therefore, having considered all the arguments, I have come to the conclusion that the applicant has not shown satisfactorily, in the time allowed, that the invention as claimed in all the claims of the application is new as required by section 1(1)(a) of the Act. I can see no way in which he can remedy this situation and therefore I decline to allow the application to proceed to grant.

5. I will follow this decision with a Statement of Reasons in as short a time as reasonably possible.

6. Since this decision is on a matter which is other than procedural the applicant has a period of 6 weeks from the date of the decision in which to appeal. I realise, of course, that he will need to see my reasons before he can make such a decision. Therefore, should it be that when he gets my Statement of Reasons he considers he has insufficient time left within those 6 weeks to reasonably consider whether he should appeal he may apply to the Comptroller for an extension. Any application for an extension must be made prior to the expiry of the 6 week period I have just set. Only one period of extension can be granted by the Office.

Dated this 30th day of May 2000

D L WOOD

Deputy Director, acting for the Comptroller

THE PATENT OFFICE

PATENTS ACT 1977

IN THE MATTER OF

Patent Application No. GB 9522134.7

in the name of Colin Rooney

STATEMENT OF REASONS

1. This is the Statement of Reasons promised in my decision dated 30 May 2000 where I refused to allow the application to proceed to grant because of the failure of the applicant in the time allowed to show that it complied with section 1(1)(a) of the Act i.e that the claims related to an invention which was new.

2. In my decision I referred to the fact that, in general, the application relates to animal husbandry sanitising compositions. For the sake of this statement I need to set out in detail the two claims of the application which have most bearing on my decision, namely claims 1 and 5.

3. Claims 1 and 5 in the form standing at 30 May 2000 read as follows:-

“(1) An animal husbandry sanitising composition, in solid form, comprising an alkali metal peroxymonosulphate triple salt and acting as a strongly oxidising source; sulphamic acid as an acid medium and chlorine acceptor; a sequestering agent in the form of an alkali metal phosphate; a surfactant and an organic source of available chlorine in the form of a chlorinated isocyanurate.”

“(5) An animal husbandry sanitising composition, as in Claim 1, wherein a typical formulation is:-

	%w/w
<i>Caro's Acid Triple Salt</i>	50.00
<i>Sulphamic Acid</i>	15.00
<i>Sodium Dodecylbenzene Sulphonate</i>	5.00
<i>Sodium Dichloroisocyanurate</i>	5.00
<i>Sodium Hexametaphosphate</i>	25.00

4. The specific composition of claim 5 is marketed as Virucidal Extra and the argument between the examiner and the applicant has chiefly centred on the date of marketing of the composition. In the opinion of the applicant Virucidal Extra was not available to the public before 30 October 1995, the date of filing of the application, whereas it was the examiner's view that on the evidence on file it was available and it was this availability which meant that claims 1 and 5 could not be regarded as representing an invention which was new.

The law

5. Section 1(1) of the Act says that:-

1.-(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say-

- (a) the invention is new;*
- (b) it involves an inventive step*
- (c) it is capable of industrial application;*
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) below;*

and references in this Act to a patentable invention shall be construed accordingly.

6. For the purposes of this statement only section 1(1)(a) above is applicable but I need also to refer to section 2 of the Act which defines what it is that allows an invention to be

taken as new. The relevant part of section 2 reads as follows:-

“2.-(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

In this particular case the argument has been about what has “been made available to the public” before the priority date of the invention, which date is the filing date of 30 October 1995.

History of the proceedings

7. The search report on the application was issued on 22 January 1997 and the application was published on 7 May 1997. Only three documents of background interest were cited in the search report which might have suggested at the time that, when the application proceeded to substantive examination, progress towards grant of a patent should have been without too much of a problem. The fact that this was not the case is attributed to observations filed under section 21 by a third party firstly on 2 March 1998, secondly on 1 June 1999 and thirdly on 1 March 2000. These observations all related to the availability of Virucidal Extra, particularly by means of written description or use, prior to 30 October 1995.

8. The first examination report was issued by the examiner on 4 November 1998 and thereafter there was considerable correspondence between the applicant and examiner until a letter from the applicant of 18 May 2000 in response to a letter from the examiner dated 11 May 2000 indicated at point 6:-

“ 6. Your paragraph 4 indicates that you are not going to be able to reach an

agreement with us on the issue of “Novelty” so we have no alternative, before taking the matter any further, to request that all document (sic) be passed on to a “senior officer” to decide the matter.....”

I will refer to the third party observations and as much of the correspondence as is necessary to explain below my reasons for refusing the application.

The third party observations of 2 March 1998 and 1 June 1999

9. In some respects these observations relate to a different perspective on the availability of Virucidal Extra compared to the observations of 1 March 2000 and arise out of a court action in which Vincent Rooney was involved in April 1997. Vincent Rooney was named as the original applicant of the application before a deed of assignment transferred the case to Colin Rooney.

10. Reference was made in the observations of 2 March 1998 to a court action in *Auchincloss v. Agricultural & Veterinary Supplies Ltd.* reported in [1997] RPC at page 649. This was a case where Vincent Rooney as one of four defendants was accused of infringing European Patent(UK) 0260293 by selling Virucidal Extra. The outcome of the case is not important in the present context but what is important are various statements on pages 682 to 684 of the decision which I shall quote as follows:-

At page 682, line 51 to page 683, line 26:-

“It is quite clear that the First Defendants have sold more product than can be accounted for by the business documents they produced. Thus the affidavit of Mr Vincent Rooney sworn in the interlocutory proceedings on 18 October 1996 admitted they had been selling Virucidal Extra since at least 26 August 1994 and that the current turnover “is running at £1.2M per annum”. That would work out to about 240 tonnes since the average selling price is £5 per kilo. It would also require purchases of about 12 tonnes of NaDCC since this ingredient is present at 5% by

weight. Yet the defendants' documents, all in, at the end of the trial, accounted for a total of only 9 tonnes of NaDCC for the whole period July 1993 to December 1996.

Conceivably, the discrepancy could have been explained. For instance, the phrase "is running at £1.2M per annum" might have been accounted for by saying it was a temporary boom in production. If there was an explanation, the best person to give it would have been the maker of the affidavit himself.

Mr Vincent Rooney did not give evidence, despite having signed a witness statement and despite being in court. When Mr Howe announced his last witness, and it was not Mr Vincent Rooney, I intimated to him that if he applied to call that person I would consider the application on its merits. I did so because at that point it was quite clear that the plaintiffs were taking a point about the discrepancy.

Mr Rooney's secretary Mrs Walsh was called (and was in my judgement a truthful and careful witness) but she had not worked for the First Defendant company before February 1995. Her sources of information for matters before that date were Mr Vincent Rooney and Mr Hunniford. I found it strange that only the secretary was called to prove what her boss would know better.

Then at line 49 on page 683:-

In cross examination he (Mr Hunniford) was asked about the manufacture of Virucidal Extra. He stated that he was not aware of any before April 1995.

Q. You are not aware of any manufacture that took place before that?

A. No, I am not aware of any.

Q. And if it had taken place, you would have been aware of it, would you not?

- A. *If it had happened on my premises, I would certainly have been aware of it.*

Later on he reiterated:

All I can say is, the first major manufacturing of Virucidal Extra, of which I was involved was at Easter of 1995...

Asked about the approximate annual turnover in kilograms he replied that he just did not know. Pressed to explain the apparent discrepancy in amounts he replied "I just do not know without sitting down and actually being shown documents and doing calculations". Asked to explain Mr Vincent Rooney's admission in his affidavit that that the First Defendants had been manufacturing Virucidal Extra as long ago as August 1994, he said that he knew nothing about that. At the conclusion of his evidence, asked by me if it would be possible for the First Defendants to be buying supplies of Virucidal Extra without his knowledge, he said that it was. This was contrary to what he had said in chief. Other than that, my impression as he left the witness box was that he probably did not really know what had been going on outside his premises, and that maybe the First Defendants had been buying Virucidal Extra on the side from another contractor. He seemed to me to be a man of ready intelligence."

11. It is very little wonder then that, in the light of Vincent Rooney's sworn affidavit referred to in the reported decision, the examiner in his first examination report dated 4 November 1998 objected to the invention defined in all the claims of the application as not being new because Virucidal Extra, on Vincent Rooney's own admission, had been on the market since at least 26 August 1994, some 14 months prior to the filing date of the application. Indeed, I observe that even Mr Hunniford spoke of the first major manufacture of the product to his knowledge being at Easter 1995, some 6 months before the filing date.

12. Vincent Rooney's response to this is best taken verbatim from his letter in reply dated 29 April 1999 where on the opening page he says:-

“The reason for this (i.e. his non-appearance in the witness box) was that my memory and event recall was extremely poor at the time because about 19 months previously, on the 2nd September 1995, whilst on a business trip in the Irish Republic I was the victim of a “hit and run” road accident and sustained severe injuries, including multiple fractures of the skull, which caused me to be kept on a life support machine for a few days and held me in an intensive care Neurosurgical Ward for some 11 days in an unconscious state. To substantiate this I attach herewith a copy of a cutting from my local newspaper “Newtownards Chronicle” dated Thursday the 26th October 1995. It was because of my poor recall, which would have been exaggerated in a witness box environment, that my Counsel decided to run the trial without my verbal contribution.”

13. This unfortunate incident and its consequences, of course, only explain Vincent Rooney's non-appearance in the witness box but later on in the same letter he refers to his poor recall leading to him mixing up two very similar products of his, namely Virucidal Extra and Virucidal Plus so that, in effect when he referred to the former in his sworn evidence he really meant the latter. He put it like this:-

“I have spent some months since your letter of the 4th November 1998 and have used my office files as a memory bank and I can now say that although line 1 of page 683 of the trial transcript/judgement states that I admitted during interlocutory proceedings (18th October 1996) that I had been selling Virucidal Extra from at least 26th August 1994 I hope that you will logically deduce from my explanation and enclosures that this is not the case and my only explanation in defence is that my memory was not differentiating between my products Virucidal Plus and Virucidal Extra.”

Most of the remainder of Vincent Rooney's letter of 29 April 1999 is an explanation of

circumstances which he believed showed that Virucidal Extra was not available on the market prior to the date of filing the application.

14. Subsequently, there was an appeal to the Court of Appeal of the High Court decision referred to above and a report of the appeal appeared as [1999] RPC at page 397. The third party observations of 1 June 1999 drew attention to this further decision making the point that although Vincent Rooney maintained that his memory lapses were continuous until after the High Court hearing, in the Appeal Court hearing neither he or his counsel made any attempt to clarify what Vincent Rooney was now alleging i.e there were the two products Virucidal Extra and Virucidal Plus, the manufacturing dates of which he had confused. The observations concluded with the statement that Vincent Rooney had not shown sufficient proof that his sworn affidavit, used as evidence in the both the High Court and the Appeal Court, was false.

15. This, indeed, was the view also taken by the examiner and reported to Colin Rooney, to whom the application had now been assigned, in a letter dated 8 June 1999. Colin Rooney's reply dated 6 October 1999 made much reference to the relative manufacturing, approval and availability dates of Virucidal Extra and Virucidal Plus but the problem for the examiner was that until Vincent Rooney was prepared to swear otherwise he had to take the affidavit sworn for the purpose of the court proceedings to be true. So, in a letter dated 11 November 1999, he proposed what seems to me to be a reasonable solution to the dilemma.

16. What the examiner said was the following:-

"I require a sworn affidavit from Mr V Rooney which should refer to (a) the medical reasons why his statement before the Court was confused and wrong and (b) the historical facts about the manufacture and marketing of "Virucidal Extra". Evidence should be attached to the affidavit in the form of at least the Expert Report of Mr McCullins, the Official Certificate and Mr Mark Squire's evidence, all referred to in your letter dated 6 October 1999."

17. During February 2000 medical reports were received from surgeons Alan G Kerr

FRCS and Dermot P Byrnes FRCS and in anticipation of these reports alone not satisfying the examiner Colin Rooney in his letter of 16 February 2000 offered to arrange for the execution of an affidavit from Vincent Rooney should it be required by the examiner. It was required and the examiner communicated this in a letter dated 6 March 2000.

18. Unfortunately an affidavit has not been filed in spite of further reminders in letters during March and April 2000. For this reason alone I believe it would have been wrong to allow the application to proceed to grant. Although I have been perfectly willing to accept that Vincent Rooney could have been confused in his affidavit before the High Court about the earliest date when Virucidal Extra had been sold, the lack of a further affidavit, as requested by the examiner, swearing that this was the case does not allow me to just dismiss the validity of the High Court evidence. This is even more the case since, particularly before the High Court no attempt was made by counsel for Vincent Rooney to explain why the latter was not being called as a witness. If, as alleged, Vincent Rooney was likely to have become confused in the witness box I would have thought it very easy for counsel to have explained that and for the deputy judge to have understood why he was not being called. Thus, failure to take that simple remedy has not helped Vincent Rooney's case in the present proceedings.

19. Normally in pre-grant proceedings before the Patent Office the benefit of the doubt is given to an applicant in a situation where it is difficult to conclusively decide an argument one way or the other. However, in the present case, without the requested sworn affidavit, I would be wrong to ignore what Vincent Rooney had previously sworn before the High Court that Virucidal Extra had been sold since at least 26 August 1994. Therefore I am forced to the conclusion that the application must fail because it does not comply with the requirements of section 1(1)(a) of the Act.

20. In order to provide a comprehensive decision and to be fair to both Vincent and Colin Rooney I shall go on to consider the other issues raised by the third set of Third party observation filed on 1 March 2000.

The third party observations of 1 March 2000

21. With reference to six enclosures the observations of 1 March 2000 provided a raft of submissions as to why the invention of the application should not be regarded as new and therefore should be refused. All the enclosures were relied on by the examiner in a letter to Colin Rooney dated 7 April 2000 as being a good reason for maintaining the novelty objection.

22. Very briefly, the enclosures were:-

- a) A copy of a sworn affidavit of Thomas Ralph Auchincloss dated 26 July 1996 and submitted in respect of the High Court proceedings referred to in my paragraph 10 above.
- b) A letter and datasheet sent to a firm called Agro-Bio by AVS (NI) Limited (Mr Rooney's company) dated 24 August 1994.
- c) A certificate issued by Ministry of Agriculture Fisheries and Food (MAFF) dated 23 August 1994 in respect of a disinfectant marketed as Virucidal Extra.
- d) A further certificate issued by MAFF and dated 6 September 1995 which certifies the suitability of Virucidal Extra for use in Great Britain as an approved disinfectant.
- e) A copy of page 21 of a publication entitled "ANIMAL PHARM" number 332, dated 15 September 1995.
- f) A witness statement of Linda Jane Walsh, dated 11 January 1997 with its Annexures 1 to 5.

23. In a letter dated 26 April 2000 the examiner made it clear that he was not pursuing the objection in respect of the MAFF certificates and so I only need to concentrate on the other

four enclosures in the remainder of this statement.

24. Mr Auchincloss' affidavit under the heading "VIRUCIDAL EXTRA" refers, in fact, to the efforts made by a company called Antec International Limited to get hold of information about the sale of Virucidal Extra in the period both before and after the filing date of the present application. In paragraph 20 of the affidavit he comes to the conclusion that there was no indication whatsoever of the product being either promoted or sold in the UK prior to a date which I take to be around September 1995. This was in spite of, amongst other things, Agro-Bio being sent the letter and datasheet referred to above as enclosure (b). In that letter there is a comment that AVS. would like to market Virucidal Extra through companies like Agro-Bio and a datasheet, which does not refer to the composition of the product, is enclosed.

25. What I infer from all this, and I admit that the evidence before me is somewhat limited, is that AVS were anticipating getting into the UK market and that up to then they were working primarily on their export market. This information is consistent with what a Mr Jacques Van't Hart of AVS had apparently told Mr Francis Auchincloss, a cousin of Thomas Auchincloss some time around September 1994. So, although I am prepared to accept that Virucidal Extra had indeed been prepared and was ready for sale prior to the filing date of the application, the letter to Agro-Bio cannot of itself prove that it was not new in patent terms being as it is an offer to sell the product but not making it available in the terms expressed in section 2(2) of the Act.

26. However, there is, to my mind, a very significant annex attached to Thomas Auchincloss' affidavit which was not referred to by Colin Rooney in his rebuttal of much else in the affidavit and that is the letter of 21 September 1994 from Jacques Van't Hart to a Mr Dudley Page of a firm called Animal Health Supplies based in Suffolk. In the third paragraph of that letter Mr Van't Hart says the following:-

"The most interesting product is Virucidal Extra, the equivalent to Antec's Vircon S, which is sold in Northern Ireland between £12.00 - £14.00 per Kg. For your sales forecast A.V.S. will sell the product to you for approximately £7.00 Kg. With large

quantities a discount is possible.”

Again, this is only an offer to sell Virucidal Extra but without evidence to the contrary I cannot easily overlook the statement about sale in Northern Ireland from the General Manager of AVS. I must therefore take this statement as *prima facie* true particularly as Colin Rooney has not discharged the onus on him to prove otherwise and once again find the claims of the application as lacking in novelty.

27. Paragraph 15 of Thomas Auchincloss’ affidavit refers to the acquisition of a sample of Virucidal Extra on 27 March 1995 which was then sent for analysis by an independent laboratory. I do not propose to rely on this information as evidence of the lack of novelty of the product since there are no details of the conditions under which the acquisition took place especially any conditions of confidentiality which may have been attached. Moreover, there is argument in Colin Rooney’s letter to the Office dated 6 April 2000 which would make it even more unsafe for me to rely on this information alone to demonstrate the failure of the application for lack of novelty.

28. As to the disclosure in the magazine called ANIMAL PHARM this, under the heading “AVS launches disinfectant in UK”, announces that AVS has launched its new multi-purpose, broad- spectrum disinfectant, Virucidal Extra, in the UK. However, on Thomas Auchincloss’ own admission at paragraph 22 of his affidavit it proved impossible, despite this announcement, to find any indication that Virucidal Extra was either promoted or sold in the United Kingdom although apparently there was information about sales in the Irish Republic and Iran. The disclosure in ANIMAL PHARM therefore cannot be relied upon of itself as denying novelty to Virucidal Extra at the date of filing the application. Which brings me to the witness statement of Linda Jane Walsh.

29. Mrs Walsh’s witness statement refers to an order for 20,000 kg of Virucidal Extra dated 7 December 1994 and received from Damik Iran, a company based in Tehran. Confirmation of this is evidenced by a copy of the letter of credit annexed to her statement. Also annexed are copies of production control cards completed by Mr Van’t Hart and relating

to the batches fulfilling the order, copies of invoices for each of the components of Virucidal Extra used to fulfil the order and a copy of an inspection document dated 24 April 1995 showing that Virucidal Extra was available for inspection immediately prior to shipment. In the case of the latter this was a document produced by an independent inspection company called SGS Redwood Limited and was necessary so that the importer could obtain an import licence. It is of course possible that the components referred to could have been used to prepare other compositions but the other annexes are consistent in describing the product ordered, prepared and inspected as Virucidal Extra. Thus, Mrs Walsh's witness statement is significant *prima facie* evidence that large amounts of Virucidal Extra had been made and were available before the earliest date of the application.

30. In response to this Colin Rooney maintains, particularly in his letter of 6 April 2000, that irrespective of the nomenclature on the Redwood document the shipment to the Middle East and, indeed, all shipments prior to the date of the application were of Virucidal Plus and not Virucidal Extra. To support this contention he has filed copies of invoices to companies in the Middle and Far East as well as letters from such companies to show typical sales and enquiries about Virucidal Plus both before and after the date of the application. Absent, though, is any evidence that would show beyond doubt that the shipment to Damik Iran referred to in the paragraph above is Virucidal Plus rather than Virucidal Extra.

Conclusion

31. I have therefore come to the conclusion that, taking everything into account, Mr Rooney at the date by which this application needed to be put in order for grant, i.e. 30 May 2000, had not satisfied the examiner on the matter of whether the invention as defined in the claims met the requirement of section 1(1)(a) of the Act that it was new.

32. As already stated in my decision of 30 May 2000 I have no option but to refuse the application. I have done this with some reluctance because some of the arguments submitted by both Vincent and Colin Rooney have suggested that there might be a measure of force in what they have been saying. However, a number of the arguments against them from the third

party and pursued by the examiner have had considerable weight and have not been overcome by a somewhat selective choice of documents in attempt to prove the opposite. It has certainly been the case that a sworn affidavit was required from Vincent Rooney to overcome what he had submitted on oath in the reported Court proceedings. In my view, a further affidavit(s) would have been needed to overcome the nature of the arguments against them in respect of the availability of Virucidal Extra before 31 October 1995. The failure to file such affidavits as clearly requested by the examiner in his letter of 11 November 1999 has therefore been at the root of my finding that the requirement of section 1(1)(a) of the Act has not been met.

33. The period for appeal is 6 weeks from 30 May 2000 which is the date on which I issued my decision. If, because of the time it has taken to issue this statement of reasons, the applicant wishes to obtain an extension to this period he must apply to the Comptroller prior to the expiry of the 6 weeks period. Only one period of extension can be granted by the Office.

Dated this 15th day of June 2000.

D L WOOD

Deputy Director, acting for the Comptroller

THE PATENT OFFICE