



Claim Form

In the HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF
ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD) 12 Feb 2021
PATENTS COURT

Fee Account
no. PBA0086995

Help with Fees
– Ref. no. (if
applicable)

H W F - HP 2021-000007



You may be able to issue your claim online
which may save time and money. Go to
www.moneyclaim.gov.uk to find out more.

	For court use only
Claim no.	
Issue date	

Claimants names and addresses including postcode

GILEAD SCIENCES INC., a corporation registered in the US state of Delaware, with
its principal place of business at 333 Lakeside Drive, Foster City, CA 94404, USA

GILEAD SCIENCES LIMITED, a company incorporated under the laws of England
and Wales whose registered office address is 280 High Holborn, London, WC1V
7EE, England



Defendant name and address including postcode

NUCANA PLC, a public limited company incorporated under the laws of England and Wales whose
registered office address is 77-78 Cannon Street, London, England, EC4N 6AF

Brief details of claim

The Claimants claim:

1. A declaration that European Patent (UK) No. 2 955 190 B1 is, and has at all material times
been, invalid.
2. An order that European Patent (UK) No. 2 955 190 B1 be revoked.
3. An order for dissemination and publication of judgment.
4. Further or other relief.
5. Costs together with interest thereon.

Value

For the purpose of CPR 3.12(1)(b) the estimated value of the claim exceeds £10 million and the
Claimants seek relief other than a sum of money. The action will need a specialist list in the
Business and Property Courts of England and Wales, namely the Intellectual Property List (ChD),
Patents Court, in accordance with CPR Part 63.

You must indicate your preferred County Court Hearing Centre for hearings here (*see notes for
guidance*)

For further details of the courts www.gov.uk/find-court-tribunal.

When corresponding with the Court, please address forms or letters to the Manager and always quote the claim number.

N1 Claim form (CPR Part 7) (06.16)

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Defendant's
name and
address for
service
including
postcode

NUCANA PLC
whose address for service is:
HGF LIMITED
Document Handling-HGF-(Leeds)
1 City Walk
LEEDS
LS11 9DX
United Kingdom

£	
Amount claimed	Unspecified
Court fee	£528
Legal representative's costs	To be assessed
Total amount	£528
Claim No.	

Does, or will, your claim include any issues under the Human Rights Act 1998? [] Yes [X] No
Particulars of Claim and Grounds of Invalidity attached.

Statement of Truth

*The claimants believe that the facts stated in these particulars of claim are true. The claimants understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

* I am duly authorised by the claimants to sign this statement

Full name: Patrick Kelleher

Name of claimant's legal representative's firm: Bird & Bird LLP



signed _____ position or office held: Partner
Claimant's legal representative (if signing on behalf of firm or company)

Bird & Bird LLP
12 New Fetter Lane,
London EC4A 1JP

Tel: 020 7415 6000
Fax: 020 7415 6111

Ref: HERE/NIXL/PEK/GLEAD.0035

Claimant's or claimant's legal
representative's address to which
documents or payments should be
sent if different from overleaf including
(if appropriate) details of DX, fax or e-
mail.

IN THE HIGH COURT OF JUSTICE

BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES

INTELLECTUAL PROPERTY LIST (ChD)

PATENTS COURT

B E T W E E N:

(1) GILEAD SCIENCES INC.

(a corporation registered in the US state of Delaware)

(2) GILEAD SCIENCES LTD.

(a company registered in England & Wales)

Claimants

-and-

NUCANA PLC

(a company registered in England & Wales)

Defendant

PARTICULARS OF CLAIM

1. The First Claimant is a US company registered under the law of the State of Delaware. The Second Claimant is registered and incorporated under the laws of England and Wales. The Claimants are part of the Gilead group. The Gilead group is a research-based biopharmaceutical leader in the discovery and development of antiviral pharmaceuticals.
2. The Defendant is a public limited company incorporated under the laws of England and Wales. The Defendant is and has at all material times been the registered proprietor of European Patent (UK) No. 2 955 190 B1 (the "**Patent**"), granted 28 March 2018. The Defendant is a biopharmaceutical company that develops anti-cancer medicines.
3. The Patent is currently in force. In a hearing before the EPO Opposition Division on 8 February 2021, the claims of the Patent were narrowed to the form set out in Auxiliary

Request 13. The Defendant has not yet applied to amend the claims of the Patent in the UK in accordance with Auxiliary Request 13. The Claimants therefore plead against the Patent as it currently stands, namely in the form as granted. Should the Patent be amended in the UK to be in accordance with Auxiliary Request 13, the Claimants' claim will be against the amended form of the Patent.

4. The Patent is and has at all material times been invalid for the reasons set out in the Grounds of Invalidity served herewith.

AND THE CLAIMANTS CLAIM

- (1) A declaration that European Patent (UK) No. 2 955 190 B1 is, and has at all material times been, invalid.
- (2) An order that European Patent (UK) No. 2 955 190 B1 be revoked.
- (3) An order for dissemination and publication of judgment.
- (4) Further or other relief.
- (5) Costs together with interest thereon.

BIRD & BIRD LLP

STATEMENT OF TRUTH

The Claimants believe that the facts stated in this Particulars of Claim are true. The Claimants understand that proceedings for contempt of court may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth. I am duly authorised by the Claimants to sign this statement.



Signed:

Name: Patrick Kelleher

Position: Partner, Bird & Bird LLP

Date: 12 February 2021

SERVED this 15th day of February 2021 by Bird & Bird LLP of 12 New Fetter Lane, London EC4A 1JP, Solicitors for the Claimants.

IN THE HIGH COURT OF JUSTICE

BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES

INTELLECTUAL PROPERTY LIST (ChD)

PATENTS COURT

B E T W E E N:

(1) GILEAD SCIENCES INC.
(a corporation registered in the US state of Delaware)

(2) GILEAD SCIENCES LTD.
(a company registered in England & Wales)

Claimants

-and-

NUCANA PLC
(a company registered in England & Wales)

Defendant

GROUND OF INVALIDITY

These are Grounds of Invalidity in respect of European Patent (UK) No. 2 955 190 B1 ("the **Patent**") referred to in the Particulars of Claim served herewith upon which the Claimants rely.

1. None of the claims of the Patent is in respect of a patentable invention in that their subject matter was obvious and did not involve an inventive step having regard to matter forming the state of the art at the priority date thereof.

PARTICULARS

- 1.1 The Claimants rely upon the following as forming part of the state of the art along with common general knowledge:

- 1.1.1 US 2003/0109697 "*Novel phosphoramidate compounds and methods for use*" (**Shepard**);

- 1.2 The Claimants will say that the Patent does not make plausible any technical contribution, and accordingly the Patent lacks inventive step and/or the disclosure of the Patent is no more enabling than that of the prior art cited above.
- 1.3 Without prejudice to the generality of the foregoing the Claimants will say that:
- 1.3.1 The Patent relates to "*nucleotide derivatives and their use in the treatment of cancer*", however the claims are not limited in extent to the treatment of any particular disease or condition. Further, the Patent describes "*Experimental data...in Table 1 illustrating the activity of compounds embodying the present invention*" ([0297]). The data provided are solely in respect of cytotoxicity measurements using an MTT assay. Such data is incapable of rendering it plausible that any particular compound falling within the claims would be suitable for the treatment of and/or achieve any therapeutic effect in the treatment of a disease or condition other than cancer, still less that all compounds falling within the claims would do so, and is not sufficient to render it plausible that any and/or substantially all of the compounds falling within the scope of the claims would achieve the asserted activity and/or therapeutic effect in:
- (a) the treatment of any given cancer
 - (b) the treatment of all cancers
 - (c) the treatment of any disease other than cancer.
- 1.3.2 In the premises, there is nothing in the Patent sufficient to render it plausible that any and/or substantially all of compounds within the scope of the claims would be suitable and effective for, and/or have a particular activity in, and/or achieve a particular therapeutic effect in, any or all methods of treatment, including but not limited to the treatment of cancer(s).
- 1.3.3 Further, and in particular, according to claim 1 as granted, X is "*independently selected from the group H, F, Cl, Br, I, OH and methyl (-CH₃)*". However, the only exemplified compounds are those in which X is F. The Patent does not exemplify any claimed compound in which X is other than F. In particular, the Patent does not disclose any claimed compound in which Y = F and X = -

CH₃, nor does the Patent disclose any of the properties of any such compound, sufficient to render it plausible that any such compound would be suitable and effective for, and/or have a particular activity in and/or achieve a particular therapeutic effect in:

- (a) the treatment of any given cancer
- (b) the treatment of all cancers
- (c) the treatment of any disease other than cancer

1.4 In the alternative, the Claimants will say that the Patent describes "*nucleotide derivatives and their use in the treatment of cancer*" ([0001]), and all of the data presented in the Patent relates to the activity of certain compounds embodied by the Patent with respect to specified cancers, accordingly, the claims of the Patent should be construed as limited to compounds for the treatment of such cancers/cancer. Such a claim would nonetheless lack a technical contribution for the reasons given above.

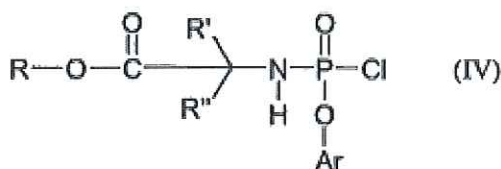
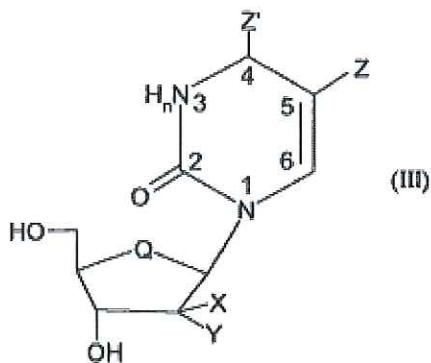
2. The specification of the Patent does not disclose the invention claimed in claims 1-11 and 13-15 (insofar as they depend on any one of claims 1-11) clearly enough and completely enough for it to be carried out by a person skilled in the art.

PARTICULARS

The matter on which the Claimants will rely is:

- 2.1 The Claimants will say that by reason of the facts and matters set out under paragraph 1.2 – 1.4 above, the claims of the Patent exceed the technical contribution to the art and are insufficient.
- 2.2 The Patent describes how to prepare compounds according to claim 1 at paragraph [0073]. This states that the process for preparation of a compound having formula (I) claimed in claim 1 is a process:

"comprising reacting of a compound of formula (III)...with a compound of formula (IV)"



2.3 The starting material of formula (III) in which Y=F and X=-CH₃ was not available to a person skilled in the art at the priority date of the Patent (21 July 2003). Such a compound was not known to the public. A person skilled in the art would not have been able, without undue burden, to synthesise such a compound of formula (III) without undertaking a research programme.

2.3.1 The decision of Arnold J in *Idenix Pharmaceuticals Inc & ors v Gilead Sciences Inc & ors* [2014] EWHC 2916 (Pat) (1 December 2014) (the "**Idenix Decision**") contained findings of fact that compounds falling within the scope of formula (III) herein could not have been synthesised by a person skilled in the art without undue burden at a priority date of 27 June 2003. The Claimants will assert that the findings of fact in the *Idenix Decision* are correct for the reasons given by Arnold J and upheld by the Court of Appeal in *Idenix Pharmaceuticals Inc v Gilead Sciences Inc & ors* [2016] EWCA Civ 1089 (8 November 2016).

3. The Patent contains subject matter which extends beyond the content of the application for the Patent as filed (the "**Application**") and the application for the parent of the Patent, EP 1 646 639 (the "**Parent Application**").

PARTICULARS

Claim 1

- 3.1 Claim 1 in the Application specified *inter alia* that "*X and Y are independently selected from the group comprising H, F, Cl, Br, I, OH and methyl (-CH₃)*". During examination this text was amended to specify in the Patent that "*X is independently selected from the group comprising H, F, Cl, Br, I, OH and methyl (-CH₃); Y is F...*". The Application provides no basis for narrowing the claim to specify that Y is F. There is no teaching in the Application to show that compounds specifically having a fluorinated pentose moiety are particularly beneficial over analogues lacking such features. The restriction to such compounds in claim 1 thus provides the skilled person with new technical information that cannot be derived from the Application.

Claim 2

- 3.2 Claim 2 is dependent on claim 1. The particulars applicable to claim 1 also apply to claim 2 of the Patent.
- 3.3 In addition, claim 2 defines position R as being selected from a limited selection of alternatives including C₁₋₆ primary or secondary alkyl; and C₁₋₆ alkyl C₅₋₇ aryl. These alternatives are not present in either claim 2 of the Parent Application as originally filed, or in the description of the Parent Application at page 7 lines 16 to 23 regarding position R. Claim 2 thus extends beyond the content of the Parent Application as filed.

Claims 3-11

- 3.4 Claims 3 to 11 are all dependent on claim 1 and claim 2. The particulars applicable to claim 1 therefore also apply to them. Insofar as they depend on claim 2, the particulars applicable to claim 2 likewise apply.

Claim 12

- 3.5 Claim 12 depends on any one of the preceding claims and specifies that when *n* is 0 each of X and Y is F. Claim 12 contains added matter for the same reason as claim 1 with respect to amendment of "*derivative or metabolite*" to "*salt, ester, or salt of such ester*". Insofar as claim 12 depends on claim 2, the particulars applicable to claim 2 likewise apply.

Claim 13

- 3.6 Claim 13 is a medical use claim. It is directed to a compound according to any one of claims 1 to 12 for use in a method of treatment.
- 3.7 Claim 13 derives from claim 17 of the Application as originally filed, which related to a compound according to any one of original claims 1 to 16. Claims 1 to 12 of the Patent do not correspond to any of claims 1 to 16 of the Application. Claim 13 therefore does not find basis in the Application.
- 3.8 As claim 13 relates to a compound according to claim 1 or claim 2, the particulars applicable to these claims likewise apply.

Claim 14

- 3.9 Claim 14 is directed to a pharmaceutical composition comprising a compound according to any one of claims 1 to 12 in combination with a pharmaceutically acceptable carrier, diluent or excipient.
- 3.10 Claim 14 derives from claim 18 of the Application as originally filed, which related to a compound according to any one of original claims 1 to 16. As claims 1 to 12 of the Patent do not correspond to any of claims 1 to 16 of the Application, claim 14 has no basis in the Application.

Claim 15

- 3.11 Claim 15 relates to a method of preparing a pharmaceutical composition comprising the step of combining a compound according to any one of claims 1 to 12 with a pharmaceutically acceptable excipient, carrier or diluent.
- 3.12 Claim 15 derives from claim 19 of the Application as originally filed, which related to a compound according to any one of original claims 1 to 16. For the same reasons as set out above for claims 13 and 14, claim 15 has no basis in the Application.

Description of the Patent

- 3.13 Page 3 line 12 to page 4 line 7 of the original description of the Parent Application provided a counterpart to claim 1 as originally filed. This was amended in the Patent in the same way as claim 1. This passage of the description is not clearly and unambiguously derivable from the Parent Application for the reasons given above in the context of claim 1.

- 3.14 Referring to formula (I), page 9 line 16 of the Parent Application explained that "*Preferably, X and Y are independently selected from the group comprising F, H and OH*". This passage in the Patent refers to X only ([0038]). There is no basis in the Parent Application for a compound of formula (I) wherein, specifically, Y is F and X is F, H or OH.

BIRD & BIRD LLP

SERVED with the Particulars of Claim this 15th day of February 2021 by Bird & Bird LLP of 12 New Fetter Lane, London EC4A 1JP, Solicitors for the Claimants.