What a Chemist Needs to Know…
… about Patents

Prepared for
SCI

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Patentability

Requirements for patentability

- Novelty
- Inventive step
- Industrially applicable
- Not excluded from patentability

US Health Warning

- The requirements for patentability in the USA have some similarities to other jurisdictions, but the way they work in practice is very different from virtually every other country (although recent reforms are bringing the USA more into line with other countries)
- Most of what follows is based on European practice, but applies more-or-less to most other countries **except the USA**

Excluded from patentability

- Not inventions:
- Methods for performing mental acts, doing business, and programs for computers are excluded “as such”

- Patents shall not be granted for:
- Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body

Industrially applicable

- Methods of contraception may be regarded as not industrially applicable if “applied in the private and personal sphere of a human being”

Novelty

- An invention shall be considered new if it does not form part of the state of the art

State of the art

- Everything made available to the public by means of a written or oral description, by use, or in any other way, before the [filing date]
- Also, earlier filed but later published patent applications in the same jurisdiction

- Includes:
- Any publication, however obscure
- Public (but not private) use, and everything that can be discerned from that use
- **Disclosures by anyone, including the inventor(s), including lectures at conferences!**

State of the art in practice

- Examiners usually search patent publications and journals

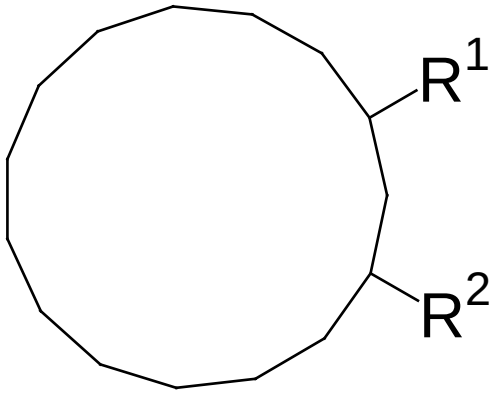
Novelty in practice

- A disclosure is typically novelty-destroying only if it discloses all the features of a claim, in combination, in a single document, or another document that it explicitly refers to

Novelty in practice

- A generic disclosure does not destroy the novelty of any of the specific possibilities falling within the disclosure
- A specific disclosure destroys the novelty of any generic feature that encompasses the specific, but not of another specific alternative (but another specific alternative may lack inventive step)

Example



A compound of the above formula, wherein R^1 is…..

Example

Claim	Prior Art Document	Novel?
Ethyl group	Alkyl group	Yes
Ethyl group	C_1 to C_6 Alkyl group	Yes
Ethyl group	Methyl group	Yes
Alkyl group	Ethyl group	No
C_1 to C_6 Alkyl group	Ethyl group	No

Conclusion

- Repeat the analysis for every claimed feature, and only if there is a novelty-destroying disclosure of all features does the claim lack novelty

- AND SOMETIMES:

- Even if there is a disclosure that is in principle novelty-destroying for each claimed feature individually, there can still be novelty for a *combination* of features that is not disclosed: this is the basis of the "selection invention"

Inventive step

- An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

- The state of the art for inventive step does not include prior-filed, later published, patent applications.

Person skilled in the art

- Has all the necessary technical knowledge and skill in the technical field of the invention, but is unimaginative and cannot invent

- There is scope for argument about what such an imaginary person should be considered to know

What is obvious?

- Different jurisdictions have different tests
- All in the end involve:
    A. Identify difference(s) between prior art disclosure and invention
    B. Decide whether it would have been obvious to modify the prior art in order to arrive at the invention
- Determined at the [filing date] of the application/patent being considered
- Hindsight must be avoided, which is difficult since step A. is based on retrospective analysis

Could/Would

- The test is not “could the skilled person have arrived at the invention” but **would** the skilled person have arrived at the invention”
- A similar consideration is “would the skilled person have had an expectation of success”

Unexpected advantage

- Often, an unexpected advantage, that could not have been predicted from the prior art, is taken as evidence of an inventive step
- Particularly relevant to “selection inventions”
- However, if the invention is already sufficiently obvious, then an unexpected advantage can sometimes be considered a “bonus effect”, which does not confer inventive step

Conclusion

- Inventive step is somewhat subjective, and there is a lot of scope for argument and different conclusions from the same facts
- During the application process, the fact that it is a two-way dialogue between the applicant and the examiner means that the applicant does get the benefit of the doubt, to some extent

Enablement

- The patent (application) must disclose the invention sufficiently clearly and completely for it to be carried out by a person skilled in the art
- Using the disclosure of the patent and common general knowledge
- Judged at the priority date
- This is what most of the specification other than the claims is aiming to achieve

Selection Inventions

The basic rules

- "Selection invention" means an invention that lies within the broad, general disclosure of a prior art document
- EPO Guidelines: "Selection inventions deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range."
- There is no legally distinct concept of a "selection invention", and the term does not appear in any patent law
- In principle, what are termed "selection inventions" are subject to the same requirements of novelty (and inventive step) as any other invention
- So the question for novelty is – does the prior art disclose the invention?

The tests – “Two list principle”

- In determining the novelty of a selection, it has to be decided, whether the selected elements are disclosed in an individualised (concrete) form in the prior art. A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features then the resulting combination of features, not specifically disclosed in the prior art, confers novelty (the "two-lists principle").

The tests – sub range from broader range

A sub-range selected from a broader numerical range of the prior art is considered novel, if each of the following three criteria is satisfied:

(a) the selected sub-range is narrow compared to the known range;

(b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range;

(c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention (purposive selection, new technical teaching).

And moreover

An effect occurring only in the claimed sub-range cannot in itself confer novelty on that sub-range. However, such a technical effect occurring in the selected sub-range, but not in the whole of the known range, can confirm that criterion (c) is met, i.e. that the invention is novel and not merely a specimen of the prior art. The meaning of "narrow" and "sufficiently far removed" has to be decided on a case-by-case basis.

And a general test

Based on the disclosure of the prior art document, would the skilled person seriously contemplate practising in the area of the alleged selection invention? (NB this is a NOVELTY question)

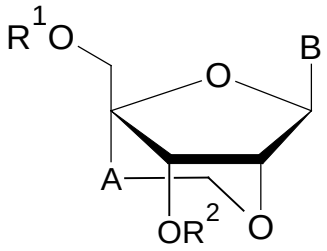
And inventive step?

For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

Inventive step usually follows quite naturally if novelty is established

Conformationally locked oligonucleotides

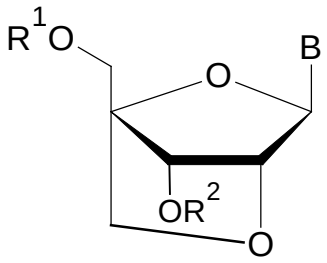
The claimed nucleoside



A is a C_1 to C_4 alkylene group

Improved duplex and triplex formation, and phosphodiesterase resistance, shown

Applicant’s own prior art



And the other prior art

And the other prior art

R^{2*} and R^{4*} together designate a biradical selected from -O-, -S, -N(R^*)-, -(CR^*R^*)$_{r+s+1}$-, -(CR^*R^*)$_r$-O-(CR^*R^*)$_s$-, -(CR^*R^*)$_r$-S-(CR^*R^*)$_s$-, -(CR^*R^*)$_r$-N(R^*)-(CR^*R^*)$_s$-, -O-(CR^*R^*)$_{r+s}$-O-, -S-(CR^*R^*)$_{r+s}$-O-, -O-(CR^*R^*)$_{r+s}$-S-, -N(R^*)-(CR^*R^*)$_{r+s}$-O-, -O-(CR^*R^*)$_{r+s}$-N(R^*)-, -S-(CR^*R^*)$_{r+s}$-S-, -N(R^*)-(CR^*R^*)$_{r+s}$-N(R^*)-, -N(R^*)-(CR^*R^*)$_{r+s}$-S-, and -S-(CR^*R^*)$_{r+s}$-N(R^*)-; wherein each R^* is independently selected from hydrogen, halogen, azido, cyano, nitro, hydroxy, mercapto, amino, mono- or di(C_{1-6}-alkyl)amino, optionally substituted C_{1-6}-alkoxy, optionally substituted C_{1-6}-alkyl, DNA intercalators, photochemically active groups, thermochemically active groups, chelating groups, reporter groups, and ligands, and/or two adjacent (non-geminal) R^* may together designate a double bond, and each of r and s is 0-3 with the proviso that the sum r+s is 1-4;

And the specific bit:

85. A nucleotide analogue according to any of the claims 83-84, wherein the biradical is selected from -O-, -$(CH_2)_{0-1}$-O-$(CH_2)_{1-3}$-, -$(CH_2)_{0-1}$-S-$(CH_2)_{1-3}$-, -$(CH_2)_{0-1}$-N(R^N)-$(CH_2)_{1-3}$-, and -$(CH_2)_{2-4}$-.

And specific disclosure of the OCH_2 linkage (same as applicant's own prior art)

Is the claimed nucleoside novel?

What do you think?

2 lists?

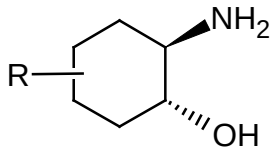
Sub-range?

What does the prior art really disclose?

What would the skilled person contemplate?

Derivatives and salts

Aminohydroxymycin



Consider how one might claim:

a) Salts of the amine
b) Prodrugs in the form of esters of the alcohol

(Let's disregard amides for the moment)

Generic disclosure

….and salts thereof and prodrugs thereof.

Or

….and salts thereof and esters thereof.

Clear?

Enabled? (Sufficiently disclosed?)

Specific disclosure

The salt may be a salt with a mineral acid, such as a sulphate, a hydrogen sulfate, a nitrate, a phosphate, a fluoride, a chloride, a bromide, an iodide, …

…or a salt with an organic acid, such as an alkyl sulphonate or an aryl sulphonate, and an alkanoic acid or an aryl carboxylic acid, e.g. a benzoate, an acetate, a methyl sulphonate, a benzene sulphonate, a toluene sulphonate, ….

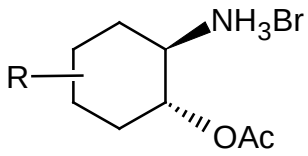
The ester may be an ester formed with an alkanoic acid or an aryl carboxylic acid, such as a benzoate or an acetate…

And to be completely sure

Add some standard experimental procedures for making salts and esters.

The infringement

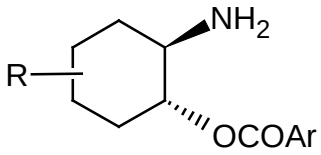
Chinese generics company comes up with:



You are delighted with your amazing foresight

But what if…

Your researcher comes up with this, which has much better bioavailability?



If Ar is Ph?
If Ar is para-bromo-phenyl?
Did you have a lucky escape?