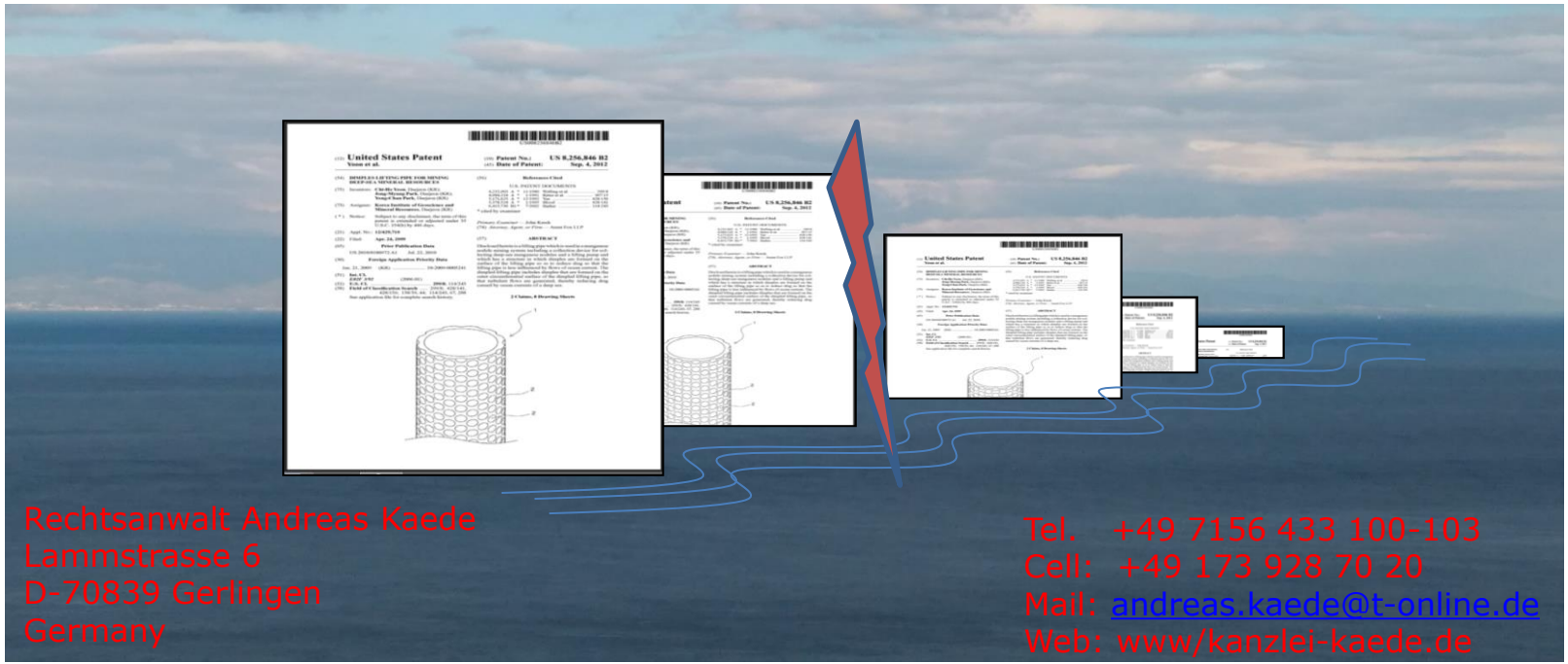
IP Licensing for DSM – Leave the Regulatory Gap or Fill it?



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IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

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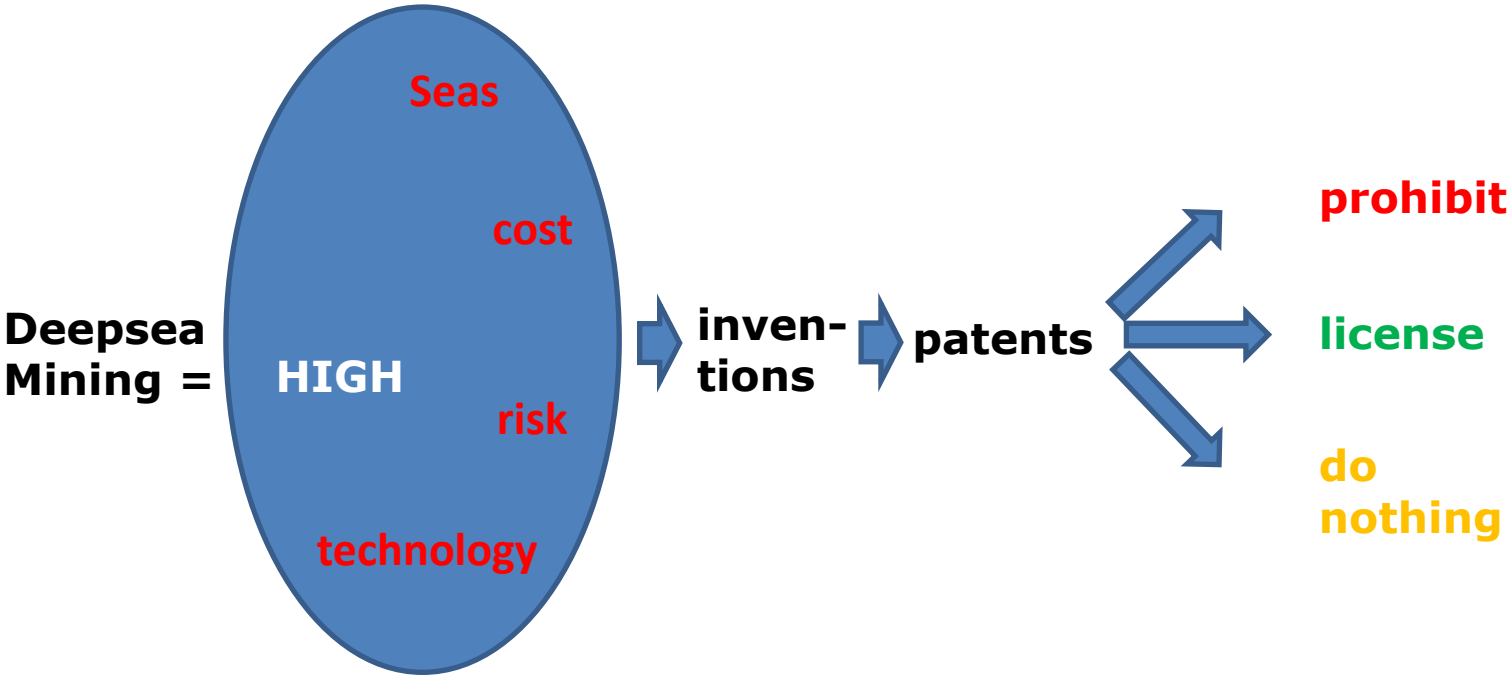

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

Patents in General:

- Lifetime 20 years from application
- Require annual extension by payment of renewal fee
- Are only valid in the countries where they are granted
- No territorial extension of patents to the High Seas/the Area

Patents and Deep Sea Mining

- over 300 returns on patent search for „Deepsea Mining", about 140 in PCT and 50-100 in major jurisdictions
- Quality of a given patent (i.e. coverage and validity) counts more than quantity
- Many patents are relatively old and close to, or over expiration time

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SECTION 2. PRINCIPLES GOVERNING THE AREA

Article136

Common heritage of mankind

The Area and its resources are the common heritage of mankind.

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

1. Introduction

1.1 DSM and innovation

1.2 relevance of patents

2. The Regulatory Gap

2.1 (Patent) Political Considerations

2.2 failed – or failing – attempts to regulate

3. Alternative Ways to a Rule

3.1 Wait for legal practice?

3.2 Industry Template?

3.3 IPR Policy?

4. The Proposed Concept

4.1 General viability

4.2 beneficiaries

4.3 Industrial scope of license

4.4 Type of IP to be licensed

4.5 Commercial Conditions

5. Conclusions

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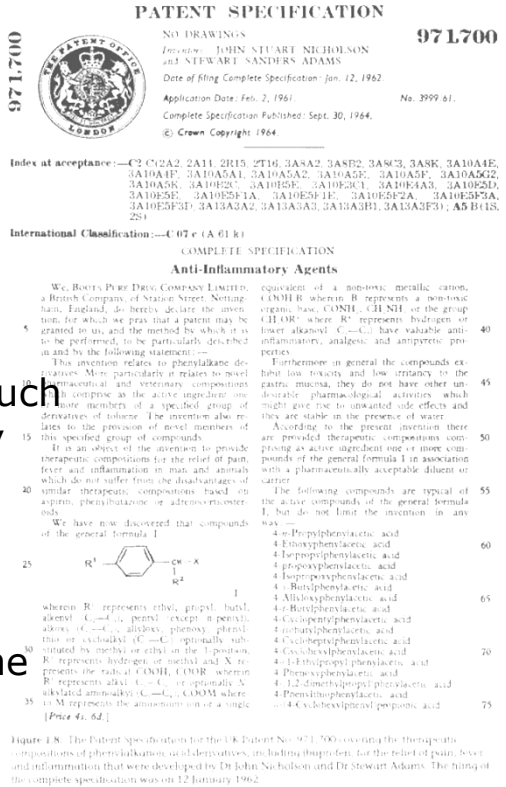
2. The Regulatory Gap

- Long standing dispute in the patent community :
  - Unethical for somebody to protect a nature based phenomenon by patents (cf. human genome)!

  vs
  - Legal uncertainty if patenting is prevented in certain areas. As long as patents are what they are, avoid such restrictions! Some authors even question mandatory licensing.

- „Bad experience" in maritime context: complex and far reaching licensing obligations for DSM one reason for the 1994 Amendment, which only allowed UNCLOS III to come into force 12 years after ist signature.



PATENT SPECIFICATION

971,700

NO DRAWINGS

Inventors: JOHN STUART NICHOLSON and STEWART SANDERS ADAMS

Date of filing Complete Specification: Jan. 12, 1962.

Application Date: Feb. 2, 1961. No. 3999/61.

Complete Specification Published: Sept. 30, 1964.

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Index at acceptance:—C2 C(2A2, 2A11, 2R15, 2T16, 3A8A2, 3A8F2, 3A8C3, 3A8K, 3A10A4E, 3A10A4F, 3A10A5A1, 3A10A5A2, 3A10A5E, 3A10A5F, 3A10A5G2, 3A10A5K, 3A10F2C, 3A10F5E, 3A10F5G, 3A10F6A3, 3A10F6D, 3A10E5E, 3A10E5F1A, 3A10E5F1E, 3A10E5F2A, 3A10E5F3A, 3A10E5F3D, 3A13A3A2, 3A13A3A3, 3A13A3B1, 3A13A3F3); A5 B(1S, 2S)

International Classification:—C 07 c (A 61 k)

COMPLETE SPECIFICATION

Anti-Inflammatory Agents

We, BOOTS PURE DRUG COMPANY LIMITED, a British Company, of Station Street, Nottingham, England, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to phenylalkane derivatives. More particularly it relates to novel pharmaceutical and veterinary compositions which comprise as the active ingredient one or more members of a specified group of derivatives of toluene. The invention also relates to the provision of novel members of this specified group of compounds.

It is an object of the invention to provide therapeutic compositions for the relief of pain, fever and inflammation in man and animals which do not suffer from the disadvantages of similar therapeutic compositions based on aspirin, phenylbutazone or adrenocorticosteroids.

We have now discovered that compounds of the general formula I

I

wherein R^1 represents ethyl, propyl, butyl, alkenyl (C—C$_5$, pentyl (except n-pentyl), alkoxy (C—C$_5$, alkylthio, phenoxy, phenylthio or cycloalkyl (C—C$_6$) optionally substituted by methyl or ethyl in the 3-position, R^2 represents hydrogen or methyl and X represents the radical COOH, COOR wherein R represents alkyl (C—C$_5$) or optionally N-alkylated aminoalkyl (C—C$_5$), COOM where M represents the ammonium ion or a single equivalent of a non-toxic metallic cation, CONHR wherein R represents a non-toxic organic base, CONH$_2$, CH$_2$NH$_2$ or the group CH$_2$OR^1 where R^1 represents hydrogen or lower alkanoyl (C—C$_4$) have valuable anti-inflammatory, analgesic and antipyretic properties.

Furthermore in general the compounds exhibit low toxicity and low irritancy to the gastric mucosa, they do not have other undesirable pharmacological activities which might give rise to unwanted side effects and they are stable in the presence of water.

According to the present invention there are provided therapeutic compositions comprising as active ingredient one or more compounds of the general formula I in association with a pharmaceutically acceptable diluent or carrier.

The following compounds are typical of the active compounds of the general formula I, but do not limit the invention in any way:—

4-n-Propylphenylacetic acid
4-Ethoxyphenylacetic acid
4-Isopropylphenylacetic acid
4-propoxyphenylacetic acid
4-Isopropoxyphenylacetic acid
4-n-Butylphenylacetic acid
4-Allyloxyphenylacetic acid
4-t-Butylphenylacetic acid
4-Cyclopentylphenylacetic acid
4-Ethylthiophenylacetic acid
4-Cycloheptylphenylacetic acid
4-Cyclohexylphenylacetic acid
4-(1-Ethylpropyl)-phenylacetic acid
4-Phenoxyphenylacetic acid
4-(1,2-dimethylpropyl)-phenylacetic acid
4-Phenylthiophenylacetic acid
4-Cyclohexylphenyl-propionic acid

[Price 4s. 6d.]

Figure 1.8. The Patent specification for the UK Patent No. 971,700 covering the therapeutic compositions of phenylalkanoic acid derivatives, including ibuprofen, for the relief of pain, fever and inflammation that were developed by Dr John Nicholson and Dr Stewart Adams. The filing of the complete specification was on 12 January 1962.

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2. The Regulatory Gap (2)

1994 Amendment to UNCLOS, Annex, Art. 5, para 1 lit b

"If the Enterprise or developing States are unable to obtain deep seabed mining technology, the Authority may request all or any of the contractors and their respective sponsoring State or States to cooperate with it in facilitating the acquisition of deep seabed mining technology by the Enterprise or its joint venture, or by a developing State or States seeking to acquire such technology on fair and reasonable commercial terms and conditions, consistent with the effective protection of intellectual property rights. States Parties undertake to cooperate fully and effectively with the Authority for this purpose and to ensure that contractors sponsored by them also cooperate fully with the Authority"

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

2. The Regulatory Gap (3)

Draft ISA Exploitation Rules (Doc. ISBA/25/C/WP1)

- Regulation 1, No. 7: „These regulations are subject to the provisions of the Convention and the Agreement and other rules of international law not incompatible with the Convention."
- Regulation 89, No. 6: „ Nothing in these regulations shall affect the rights of a holder of intellectual property."

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

3. Alterative Ways to a Rule

- **Case Law** – uncertain when emerging; different judgments from different jurisdictions
- **Template Agreement** – cases outside consortia not covered; antitrust law a concern
- **IPR Policy** – instrument „below" treaty law, suitable for e.g. standardization environment; also applicable for the delimited and regulated system of DSM; however, the same body who had to decide on introduction of licensing into the Exploitation Rules would also have to decide here (Council for ISA). Plus: non-signatories of the Policy would not be bound by it.

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

4. The Proposed Concept

General viability

- The chance: previous attempts („old" provision in UNCLOS 1982; BBNJ Art. 12) may have demanded too much; now, demanding less may be better than the gap we face
- General political context has changed since 1982
- High invest of SME market entrance needs protection

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

4. The Proposed Concept (2)

Beneficiaries (whom to grant the license?)

- No focus on DC‘s and Enterprise necessary
- The producer of the product or process, because
  - mere use would happen outside of national jurisdiction, i.e. not in a patent country
  - Lower royalty yield justified because „fair reward“ to inventor more important than earning money

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

4. The Proposed Concept (3)

Industrial Scope of the License

- Right to make, and sell the product thus made
- Limits:
  - License to be non-exclusive
  - Licensor may cap the quantity of products made by Licensee in view of his own production capacity

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

4. The Proposed Concept (4)

Type of IP to be licensed

- Patents applied for or in force in the licensed territory
- Essential patents", i.e. those which cannot be circumvented technically other than with improportionate effort
- Problem: no authority in place to determine „essentiality" in the given case

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

4. The Proposed Concept (5)

Commercial Conditions: FRAND

- **F**air, i.e. commensurate with law and the ethics of the trade;
- **R**easonable, i.e. both bearable for licensee in view of his other cost, and sufficient reward for licensor on account of his innovation efforts;
- **N**on-**D**iscriminatory, i.e. neither arbitrarily different treatment of equal situations, nor arbitrarily equal treatment of different situations.

IP Licensing for DSM – Leave the Regulatory Gap or Fill it?

5. Conclusion

- Licensing obligations seem to be the unwanted child of deepsea mining regulators. This attitude as such does not remove the potential threat from patents to the exploitation of the common heritage at seafloor level.

- Absent any specific provision in the DSM Exploitation Rules to come, a (perhaps remote) chance exists to introduce a licensing régime by way of an IPR Policy.

- A moderate approach (e.g. Essential Patents only, FRAND conditions) might induce also the opponents to agree to a respective instrument outside the strict cadre of the Mining Code.