Law, Software, & Cheminformatics: Copyright, Taxes, and Legal Issues

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Abstract: In this communication we summarized our previous in-depth review (Current Topics in Medicinal Chemistry, 2008, Vol. 8, No. 18.) on the legal aspects of the use of software and computational models in Chemoinformatics. An overview of relevant international tax issues on the use of software is also presented.

1. Introduction

The uses of Bioinformatics software is strongly related, but not limited, to the development of Quantitative Structure-Activity Relationship (QSAR) models [3]. These QSAR models connect the structure of compounds of low molecular weight, nucleic acids (DNA and RNA), and proteins with the biological function. The use of this type of software allows researchers designing and/or predicting new promising compounds [5].

The relationship between Bioinformatics and the law spans a wide range of different issues including intellectual property, licensing legislation, regulation, product development as well as corporate legal issues [9]. In our previous work, we described the various legal procedures that are available to protect software, the

acceptance and legal treatment of scientific results and techniques derived from such software, as well as some of the specific tax issues from the computer programs field [9a].

2. Results and Discussion

LEGAL PROTECTION OF SOFTWARE

There is no single method of legally protecting software. In fact, no unique international regime exists to address software protection [10].

COPYRIGHT

The most significant international treaties relating to copyright protection are the Berne Convention, the Universal Copyright Convention [14] and certain provisions of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement [15]. Software is protected by copyright throughout the E.U under the Community Directive on Software Copyright (91/250/EEC Directive). On a practical level, software vendors use multiple levels of Protection: trade secret rights, publishing "object code", binding users by contract, and increasingly- seeking patent protection [13].

PATENT PROTECTION

A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. So, patents require an inventive step, an assessment of industrial applicability and should undergo an examination procedure [18]. The law relating to the patentability of software is still not harmonized internationally [13]. The most widely followed doctrine governing the scope of patent protection for software related inventions is the "technical effects" doctrine, first promulgated by the European Patent Office (EPO) [10].

TRADE SECRET PROTECTION

"Given that access or non-access to the source code is such a key computing issue and that most proprietary software owners make great efforts to protect such code as confidential (non-disclosed) information, the relevance of trade secret law is immediately obvious" [19].

TRADEMARK PROTECTION

A Trademark is understood to be a brand or medium that is capable of being represented graphically, and which is capable of distinguishing goods or services of one undertaking from those of other undertaking. It may consist of words, designs, letters, numerals or the shape of goods or packaging [20]. The inherent limitations of the territorial application of trademark laws have been mitigated by various intellectual property treaties, foremost amongst which is the TRIPS. It establishes legal compatibility between member jurisdictions by requiring harmonization of applicable laws. International trademark issues are also governed by the European Community Trademark (ECT), the Madrid Agreement and the Madrid Protocol [21, 22].

TAX ISSUES FOR SOFTWARE

Tax systems depend of each internal country regulation, and for that reason taxation of cross border transactions relating to computer software, has always been a matter of debate. The payment for the use of computer programs is classified as a `royalty´. According to the OECD Model Tax Convention on Income and on Capital (Article 12.2), the term "royalties" means payments of any kind received as a consideration for the use of, or the right to use, any copyright of literary, artistic or scientific work including cinematograph films, any patent, trade mark, design or model, plan, secret formula or process, or for information concerning industrial, commercial or scientific experience [20, 26]].

REGULATORY USES OF QSAR

The challenge for bioinformatics and computational biology is in the validation and acceptance of new scientific methods and the results derived from software. The impact of the EU regulatory framework for QSAR provides some experience on how to address the issue of validation and acceptance of new approaches. Under Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), all chemicals produced or imported in quantities of more than a one tons per annum (tpa) in the European Union, need to be assessed for human and environmental hazards. [29]. The REACH text refers to the need to demonstrate the validity of the QSAR used [33]. It is anticipated that validity will make reference to the internationally agreed OECD principles for QSAR validation already described [29, 31].

Conflicts of Interest

The authors declare no conflict of interest.

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