

Protecting Microbiological Inventions

A Summary of legalities resulting from recent decision by Supreme Court of Germany

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In a basic decision of March 11, 1975, the Federal Supreme Court of Germany for the first time expressed its opinion on the numerous problems arising in connection with the protection of microbiological inventions. The following is a summary of the legal situation resulting from said decision which has far-reaching consequences for pending and especially for future patent applications in the microbiological field.

1. PATENT CATEGORIES

a) *Protection for a new microorganism itself* is allowable if the inventor shows a *reproducible method*, i.e. a method which can be repeated with a sufficient chance of success, for obtaining the microorganism. From the decision it can be taken that under the same conditions claims, which are directed to the propagation of microorganisms, are also allowable.¹

b) *The reproducible method* for producing a new microorganism has to be disclosed in the *original specification* or — if priority of a previous application in a foreign country is claimed — in the specification of the previous application.

2. UNITY

An application does not necessarily become nonuniform by the combination of two related strains of microorganisms in one application, if the invention is based on a *complex — though perhaps not novel — technical problem*.

3. DEPOSITION

The Federal Supreme Court confirms the practice which has been existing for years that in the case of inventions which make use of the metabolism of a microorganism;

a) the microorganism must be deposited at a depository having an established reputation in science at the latest when the application is filed, and,

b) the depository and the designation of the strain (deposition number of the strain) must be stated in the original specification.

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Deposition at a foreign depository is considered to be sufficient.

If priority of a previous application in a foreign country is claimed, the microorganism must be deposited at the latest when the foreign application is filed.

4. PERIOD OF DEPOSITION

Provisions must be made at the depository that for an adequate period of time *after expiration of the patent the microbiological material is still available* to persons skilled in the art for reproducing the formerly protected invention.

5. DECLARATION OF RELEASE AND DATE OF RELEASE

a) *Upon deposition* of the microorganism, the applicant must make an *irrevocable declaration at the depository*, that upon the first publication of the application the microorganism will be made available to third parties by the depository. (Since the microorganism has to be deposited at the latest when the application is filed, the declaration of release must also be made at that point of time.)

b) When the applicant deposits the microorganism, he can demand that the third party to which a culture of the deposited strain is handed over accepts an obligation towards the applicant neither to pass on the sample to other persons nor to remove it from the purview of the German Patent Law during the period of patent protection. The person obtaining the culture must make himself known to the applicant and especially state his name and address.

Comments to Item 5

The provision that the deposited microorganism has to be released to third parties when the application is published for the first time has serious consequences. Normally the first publication of an application is the laying-open for public inspection, which takes place 18 months after the filing date or — if a priority of a previous foreign application is claimed — 18 months after the priority date. The laying-open does not give the applicant any rights of injunction. Thus, in most cases, the applicant is forced to release his microorganism to third parties at a point of time when he has not reached effective protection.

This unsatisfactory situation may be slightly improved by applicant requesting examination immediately upon filing the application and simultaneously asking the German Patent Office to speed up the examination

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a great difficulty for Europeans trying to license an American firm. This may be one of the main reasons why you should consider doing business with Quebec. Not only are we looking for new technology, but Quebecers are, at the crossroad of three cultures in America, and having also received a large contingent of emigrants, are well prepared to accept European technology. Quebecers do not suffer from the "not-made-here-complex". Quebec may be a natural platform for your technology in America. Quebec is your America.

A Look at Government Patents

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of Justice participated, but did not vote for or against the report of this study group.

Their conclusions, which are recommendations to Congress for possible legislation, are documented in the "Report by Task Force #1 of Study Group #6, Commission on Government Procurement", submitted in November, 1971.²³ It describes a government patent policy in the public interest and I urge the patent bar to take a position on its recommendations.

Some of its highlights:

- (a) a single government-wide Patent Rights R&D contract clause
- (b) exclusive commercial rights to contractor for three years after issuance of the patent, after which the contractor may be required to grant non-exclusive licenses
- (c) royalty free license for government
- (d) a Government Patent Review Board
- (e) provision requiring "utilization" by contractor to continue exclusive commercial rights
- (f) provision for "march-in" or required licensing in event of non-utilization by contractor.

The "bonus" of such a policy as recommended above is tremendously reduced bureaucratic requirements which will be a significant savings to both our government and its contractors.

Conclusion

A sensible government patent policy which will provide the necessary incentives to industry to bring the undeveloped research advances of government-funded research forward to the marketplace for public use and benefit is urgently needed. Such a result can only strengthen the patent system of our country, in which system each of you is involved.

- ¹ University Licensing Conference, Case Western Reserve University, Cleveland, Ohio October 15, 16, 1974.
- ² S. Gee "Foreign Technology and the United States Economy" *Science* 187, 622 (21 February 1975).
- ³ A. Ezra "Technology Utilization: Incentives and Solar Energy" *Science* 187, 707 (28 February 1975).
- ⁴ Article I, Section 8. *Constitution of the United States*.
- ⁵ *Annual Reports on Government Patent Policy*, Federal Council for Science and Technology, (Through 1973). Available from U.S. Government Printing Office.
- ⁶ Government Patent Policy Study for the FCST Committee on Government Patent Policy by Harbridge House, Inc., Contract 7-35807, May 17, 1968.
- ⁷ Public Citizen, Inc. et al v. Arthur F. Sampson, Acting Administrator, General Services Administration, Civil Action No. 781-73, U.S. District Court for the District of Columbia. (Public Citizen 1)

- ⁸ Order and Judgement in U.S. District Court for the District of Columbia January 17, 1974 re: Civil Action 781-73.
- ⁹ Department of Justice Memorandum by Assistant Attorney General Cramton, October 10, 1972 re Constitutionality of Prospective Allocation of Rights in Inventions. (This issue is treated fully in the government's brief in PC II. See BNAPTC Journal, 3/6/75, pp. 01-09.
- ¹⁰ Public Citizen, Inc. et al v. Arthur F. Sampson, Administrator, General Services Administration, Civil Action No. 74-303, U.S. District Court for the District of Columbia. (Public Citizen II)
- ¹¹ Testimony of Thomas E. Kauper, Assistant Attorney General, Antitrust Division, U.S. Department of Justice before Subcommittee on the Environment, Committee on Interior and Insular Affairs, House of Representatives, 1 February 1974.
- ¹² It is interesting to review the arguments of Justice against the now discontinued patent pool policies of the auto industry in the well-known "smog" case (U.S. vs. Automobile Manufacturers Association, Civil No. 69-75-JWC (CD Cal 1969) and the aircraft industry in their 40-year pooling arrangement (U.S. vs. Manufacturers Aircraft Association, 5 Trade Reg. Rep. para 45,072 (S.D.N.Y. 1972) complaint). It appears required non-exclusive licensing of undeveloped technology results in a "government patent pool" with the same negative effect upon innovation.
- ¹³ *National Journal Report*, pp. 1774-75, 23 November 1974
- ¹⁴ Letter T. E. Kauper, for Department of Justice, to S. Weisbard, attorney for Salk Institute, February 10, 1975.
- ¹⁵ Shiley v. Weinberger, et al C.A. No. 74-479 (25 March 1974) U.S. District Court for the District of Columbia
- ¹⁶ Letter from Stanford to Department of the Air Force, July 13, 1971. (Stanford File Eng. 406)
- ¹⁷ Letter from Department of Air Force to Stanford, October 6, 1971. (Stanford File Eng. 406)
- ¹⁸ Private communication, 1974, attorney for company X to N. Reimers, Stanford University (specific citation omitted with intent).
- ¹⁹ Private communication, 27 November 1974. T. Arnold, Arnold, White & Durkee, Houston, Texas to Congressman O. E. Teague. Re Compulsory Licensing Provisions in ERDA legislation.
- ²⁰ Public Communication February 1975. Ralph Nader, Public Citizen, donation solicitation. "In addition to numerous pending cases, obtained court orders through Public Citizen lawyers — preventing the General Services Administration from permitting valuable patents developed at Government expense from being given away free, on an exclusive basis, to private companies."
- ²¹ Meeting of Board of Trustees at Annual Conference, Licensing Executives Society (USA), October 6, 1974.
- ²² Los Angeles Times, March 4, 1975, part III, page 10
- ²³ Report by Task Force #1 of Study Group #6, Commission on Government Procurement. "Allocation of Rights to Inventions Made in the Performance of Government Research and Development Contracts and Grants" November 1971.

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proceedings. For foreign applicants it is advisable to file the German application as soon as possible after having filed the application in the foreign country in order to lose the least possible amount of time of the eighteen-month period. By proceeding in this way, the chances increase that the first publication of the application will be the publication for opposition purposes, which imparts provisional, full patent protection.

For pending applications, it is advisable to make a declaration of release at the depository on the condition that the interested third party undertakes the obligations as mentioned above. Since a completely new legal situation results from the decision of the Federal Supreme Court, it should be possible to make the declarations of release which are lacking in pending applications at least during a transition period. Probably the examiner will request that the applicants make a declaration of release

during the examination procedure.

It is to be assumed that when the microorganism is deposited in a foreign depository and when the declaration of release is made at said depository, this declaration will be effective only for the Federal Republic of Germany if the declaration guarantees that it includes the release of the microorganism for export to the Federal Republic of Germany.

*If no repeatable method for producing a microorganism can be stated, a method claim, e.g. for the production of the product obtained by means of the microorganism, or a use claim may be suitable (remark of the authors).

9. Marketing
10. Loyalty & Secrecy
11. Modifications
12. Quality control (Trademarks)
13. Prices & Payments, Escalation
14. Taxes, Levies, Approvals & Clearance
15. Promotion - Joint committee
16. Guarantees
17. Hardship, Force majeure
18. Enter into force, Duration, Termination
19. Effects of termination - Breach
20. Legal succession
21. Choice of law and language, Notice, Disputes

Options, Rights of First Refusal

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from operating the refreshment room.

Thus, when a license contains both an option to determine the agreement and a right of first refusal to the licensee, the licensor can determine the license and commence operations itself without infringing the licensee's right of first refusal.

CITATIONS

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|------|-----------|-------------------------|
| (1) | (1946) | S.A.S.R. 17 |
| (2) | 47 S.R. | (N.S.W.) 315 |
| (3) | (1954) | 92 C.L.R. 245 |
| (4) | (1973) | 3 W.L.R. 884 |
| (5) | (1960) | Od. R. 465 |
| (6) | (1963) | N.S.W.R. 815 |
| (7) | (1972) | V.R. 737 |
| (8) | (1970) | 91 W.N. (N.S.W.) 222 |
| (9) | (1971) | 1 N.S.W. L.R. 735 |
| (10) | (1960) | S.C.R. 126 (Canada) |
| (11) | (1969) | 91 W.N. (N.S.W.) 468 |
| (12) | (1971) | 3 W.L.R. |
| (13) | (1970) | 45 A.L.J.R. 102 |
| (14) | (1974) | All. E.R. 161 |
| (15) | (1904) | 1 Ch. 305 |
| (16) | (1974) | 47 A.L.J.R. 606 |
| (17) | (1970) | 45 A.L.J.R. 102 |
| (18) | (1856) | 22 Beav. 625 |
| (19) | (1897) | 1 Ch. 937 |
| (20) | (1960-61) | 34 A.L.J.R. 491: (P.C.) |
| (21) | (1901) | 2 Ch. 37 |
| (22) | (1921) | 1 A.C. 85 |

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View of East-West Cooperation

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This is not the place to go into details of different contract clauses. I think though that some main aspects should be outlined. Let us therefore take a brief look at this model of some important clauses in a cooperation agreement:

Main Clauses of a Cooperation Agreement

1. Parties to the Contract - Situation & Intentions
2. Object and Scope - (Definitions)
3. Grant of rights
4. Documentation
5. Technical assistance
6. Training
7. Improvements, R & D, Information
8. Production etc. / Deliveries

You will immediately recognize many items. In a cooperation agreement, however, they take on a somewhat different aspect in view of the long-term and the mutual interests created by the cooperation. Let us pick two central questions.

The first is the question of guarantees. In a straight delivery of goods this could be very difficult. In a cooperation agreement it forms an essential part of the cooperation atmosphere. The other is the question of what to do when things turn out otherwise than expected. This stresses the importance of a working committee to smooth the way. All problems of this kind should be put before that committee for amicable settlement at once.

Usually, misunderstandings and difficulties arise over special questions regarding performance: quality, quantity, questions of service, etc. Very often an arrangement for quick and simplified arbitration of particular trouble points would clear the way for continued peaceful cooperation. In more important cases, however, a broader arbitrational solution is required. Very often both parties will accept arbitration in a third country, such as Switzerland, Sweden, or Austria, and they will then also agree on the use of that country's law both with regard to material and procedural questions.

Considerable Cost

Negotiating a contract of this type takes time and implies considerable cost. A fairly moderate Norwegian turnkey contract for delivery of a factory inclusive of recipes cost a quarter of a million N.Cr. For this reason it is imperative that the parties should take a good look into the different aspects of a cooperation: technical matters, marketing, finance, and the legal implications at a fairly early stage. A team representing these aspects should undertake a functional analysis of the project to ensure practical solutions. At a given stage these elements should be put before a legal expert on East-West matters, and he should preferably also take part in the final contract negotiations.

To conclude, however, let me stress one point. Many legal and economic specialists tend to prefer the more complex forms of cooperation, as if sophistication was a goal in itself. Let us be reminded of the old saying that, "the proof of the pudding is in the eating." If we can create good, simple, and effective cooperation, it is extremely valuable simply because it is easier to operate and could therefore be more efficient.

In the final analysis we are dealing with human cooperation. Contracts, though important, provide only the framework.