CASE HISTORY OF JAVID-SETTLAGE UREA-SUGAR SOLUTION INVENTION

U. S. Patent No. 2,960,439
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The product embodying the invention of U. S. Letters Patent No. 2,960,439 is a lifesaving product that would never have been made available to the public if it had not been for the incentives provided by the patent system.

The Javid-Settlage invention is a sterile solution comprising a combination of sterilized lyophilized urea and sugar suitable for injection in human patients for the purpose of reducing intracranial fluid pressure. The product is effective, without adverse side effects, in bringing about such pressure reduction resulting from a brain tumor or a severe head injury. Properly used, it achieves this purpose to the point where brain surgery is made possible when otherwise, due to the pressure, such surgery would be out of the question as too hazardous. Thus, the product, while of very limited use, in fact, permits the saving of human lives.

A description of the invention was published in March 1956. From that time and until almost a year later no pharmaceutical or drug manufacturer had shown the slightest interest in the product or had been stimulated by the published description of the invention to approach the inventors or the University regarding it. In fact, one firm even declined to cooperate in the preparation of experimental samples for clinical trials.

In March 1957, just within the one year's grace period beginning with the date of publication after which a statutory bar would have existed against filing a patent application, an application was filed on the invention. As a result of the potential availability of some patent protection a single company undertook a substantial program to develop the invention and clear it through the Food and Drug Administration. A patent license was subsequently issued to such company in mid-1958. Such license was exclusive for a limited time, the exclusivity being conferred in consideration of that company's agreement to complete the necessary development work to bring the product to the market stage. This agreement caused that company to expend approximately $400,000 in development and premarketing promotional work even though the estimated potential sales of the product were only about $50,000 per year.

In view of the applicable facts in this situation as briefly outlined above it is believed that the following conclusions are valid:

1. Had no patent application been filed the publication of March 1956 would have effected a dedication of the invention to the public within one year and it is extremely unlikely that any drug manufacturer would have developed the invention to the point of offering a product on the market for all competitors, with literally no development expense, promptly to imitate. As a consequence, the invention would most likely still be lying dormant and undeveloped.

2. The expenditure of $400,000 prior to the sale of one unit of the preparation would never have been made without the incentive made possible through a limited term exclusive license under the patent system, which offered the license holder an opportunity to recoup its expenses.

The foregoing is believed to be a classic example of the operation of the U. S. patent system in the transfer of technology from a University environment into use for the benefit of the public.

The facts in this situation clearly evince the critical nature of the time requirement, where publication has already occurred to develop a patent position which here was essential to the transfer of the particular technology into public use. In this situation, had the research protocol been available to the public, as through the provisions of the Freedom of Information Act, such availability would obviously have preceded the publication of a description of the invention on March 1956 and a statutory bar against patenting would have become effective. Had this occurred it is unlikely that this lifesaving invention would ever have been used for the benefit of the public.

It is submitted therefore, that the early availability to the public of all research proposals and protocols, without distinction as to the presence or absence of potentially patentable subject matter in such proposals or protocol could adversely affect the public interest.