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THE PATENT SYSTEM: ITS ECONOMIC AND SOCIAL BASIS

STUDY OF THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

EIGHTY-SIXTH CONGRESS, SECOND SESSION

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FOREWORD

This study was prepared by Victor Abramson, economic adviser to the U.S. Treasury Department, for the Subcommittee on Patents, Trademarks, and Copyrights as part of its study of the U.S. patent system, undertaken pursuant to Senate Resolution 240 of the 86th Congress. Covering a report actually prepared in 1947 for the Patent Survey Committee, a Presidential Commission appointed to examine the patent system, it is now being published for the first time, with minor revisions, in connection with the study program being conducted under the supervision of John C. Stedman, associate counsel of the subcomittee. It will be followed by a companion study, also prepared by Mr. Abramson, entitled "Patent Abuse—A Plan for Its Control."

The need for a thoroughgoing and realistic analysis of the economic forces that underlie the patent system has long been apparent, and the subcommittee has attempted to meet this need to some extent. Several of its studies and much of its inquiry have been directed to the economic workings of the system. These previous efforts to understand and analyze the economics of the patent system reached their peak with the publication earlier of our Study No. 15, prepared by Prof. Fritz Machlup, entitled, "An Economic Review of the Patent System." "The Patent System: Its Economic and Social Basis," by Mr. Abramson, provides a valuable addition to the literature on this subject. It takes on added significance in providing the economic foundation for the concrete proposals that the author makes in his companion study on patent abuse.

Mr. Abramson is well qualified by background and experience to deal with this subject. As a long-time economist with Brookings Institution he gave extensive attention to the role of Government in the economic life of the Nation, including its administration of the patent system. His work in this field culminated in his coauthorship of a landmark study entitled "Government and Economic Life." During World War II, he acted as an economic adviser to the Alien Property Custodian, in which capacity he devoted much attention to the administration of enemy-owned patents and patent rights seized pursuant to the Trading With the Enemy Act. These experiences made him a natural selection for the post of economic adviser to the Patent Survey Committee.

In publishing this study, it is important to state clearly its relation to the policies and views of the subcommittee. The views expressed by the author are entirely his own. While the subcommittee welcomes the report for consideration, its publication in no way signifies agreement with the statements contained in it. The publication does, however, testify to the subcommittee's belief that the study represents a valuable contribution to patent literature and is in the public interest.

JOSEPH C. O'MAHONEY,
Chairman, Subcommittee on Patents, Trademarks and Copyrights, Committee on the Judiciary, U.S. Senate.

September 8, 1960.

PREFACE

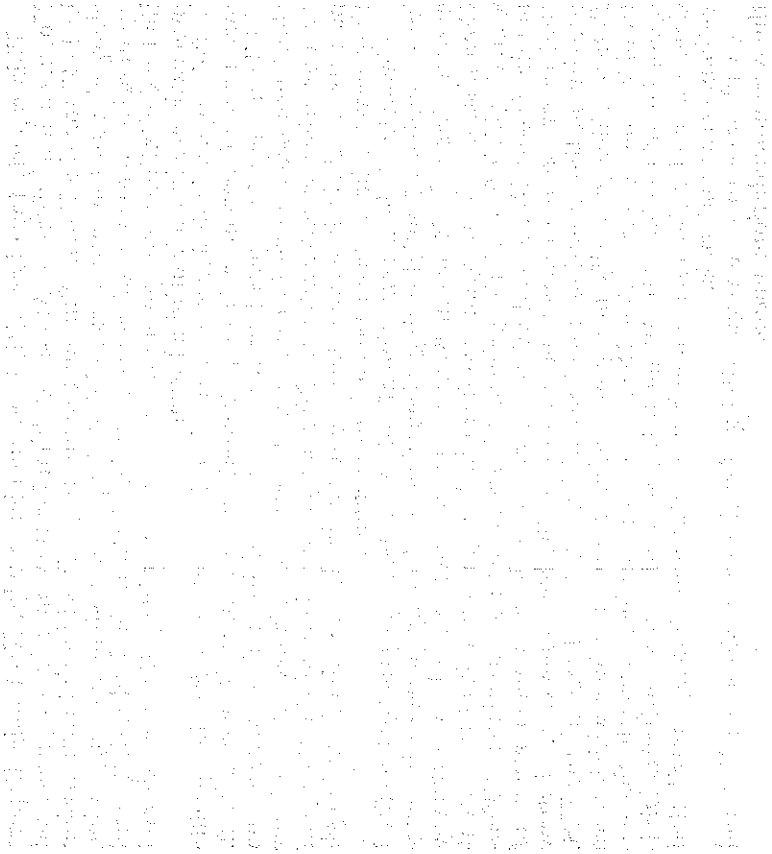
This report, together with a companion study, Economic Report No. 2, entitled "Patent Abuse—A Plan for Its Control," was prepared in 1947 for the Patent Survey Committee, a Presidential commission charged with the task of examining the patent system and suggesting appropriate measures of reform. It has been revised editorially and its legal citations brought up to date, but essentially the analysis and proposals are in their original form.

This report is designed to provide a frame of ideas for the specific measures of patent reform presented in Economic Report No. 2. While it may be separately read, in view of its limited purpose no effort has been made to cover exhaustively the history either of our own or other patent systems. Nor have other views of the theory of patents or their functions been systematically examined, although they have, I hope, been taken into account.

Throughout the preparation of both reports, I was greatly benefited by a number of enlightening discussions and many provocative suggestions from W. Houston Kenyon, Jr., counsel to the Patent Survey Committee. Mr. Kenyon also furnished a legal analysis of the patent system which formed the principal basis of the legal sections of Economic Report No. 2, and advice in phrasing the recommendations of that report so as to make them more intelligible to lawyers. I drew heavily on the extensive experience of Mr. P. J. Federico of the U.S. Patent Office to clarify in my own mind many questions which were troublesome to me. The Department of Justice, through the cooperation of the late Mr. Wendell Berge, head of the Antitrust Division, and under the direction of Mr. E. Houston Harsha, contributed valuable case materials.

I will have to take responsibility for the conclusions reached and the recommendations made.

VICTOR ABRAMSON.



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CHAPTER I

THE ROLE OF PATENTS IN A COMPETITIVE SYSTEM

A. EARLY ORIGINS

It may appear as a surprising fact that the English patents for inventions, which later furnished the model for our own patent system, first came to prominence as an instrument through which the Crown exerted national power to control industry and commerce. In an adapted form, patents survived the emergence of a system of competitive enterprise, and eventually counted among their advocates some of the leading writers in the liberal tradition. Today patents occupy an important role in every industrialized society which places any significant reliance upon private enterprise.

In England, patents grew to importance during the reign of Elizabeth beginning in the middle of the 16th century. At that time advances in the arts were infrequent and interchange of new ideas was slow. England was in many respects industrially less advanced than France and the Lowlands, and it appeared that the best opportunity to develop new industries and trades was to encourage craftsmen to migrate to England to teach their skills, and tradesmen to come for the purpose of opening up new commerce. Patents were used to provide such encouragement, and they were thus granted for "first importation" and for technology new only in England, as well as for "new inventions" in the narrower sense.

At the beginning, the chief problem was to break down the existing monopolies of manufacture and commerce held by the towns and guilds. Patents were used as a means of asserting national power to protect new workmen and traders coming in from abroad, and often merely granted to them permission to practice their arts or trades in the fields or territories then monopolistically controlled by local groups. As national power grew, however, and industry and commerce expanded, patents emerged as an instrument of industrial regulation. They came also to be used increasingly for revenue purposes, and as a means of bestowing personal favors, and they were extended to cover industries and trades already well established. Their use to encourage "invention," even in the sense of "first importation," diminished in importance, and their grant in monopolistic forms increased.

Opposition to patents arose from many sources in the latter part of the 16th century. The accumulation of capital and the influx of Protestant refugees representing a new source of labor brought pres-

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sure for greater freedom of enterprise. And there were outcries against the arbitrary and high-handed tactics of patentees and the high prices which many of them were charging for necessities. The towns and guilds, when they could not reach agreement with patentees, resented the latter's intrusion, but they were already declining in power. The sentiment grew that patents, far from encouraging enterprise, were proving a burden.[1]

As patents grew in number and came to be used for many purposes, the courts applied to them an important distinction under the common law. Those which were granted for new manufactures or for introducing new trades were held to be lawful, but those in industries or trades already established were declared contrary to the common right of every citizen to enter those fields as a means of earning a living.[2] The courts had no means, however, of preventing the issuance of unlawful patents and they remained common, and in many instances were successfully enforced, up to the enactment of the Statute of Monopolies (1624) in the reign of James I.

This statute provided that all monopolies before or thereafter granted should be "utterly void" and should be judged according to the common law. It exempted from its operation, however:

> * * * letters-patent and grants of privilege * * * of the sole working or making of any manner of new manufactures, * * * to the true and first inventor and inventors of such manufactures, which others, at the time of making such letters-patent and grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient. * * *

Patents for inventions thus for the first time received express legislative sanction in an act which sought to outlaw monopolies generally, and they have since that time enjoyed a favored position among monopolies.

Other forms of monopoly were not, however, wholly eliminated. The Statute of Monopolies did not deal with charters, and after its enactment, this latter form of monopoly grant continued for a long time to be employed for many of the purposes for which patents had been used.[3] They were particularly important in encouraging risky ventures such as settlement of the New World or the conduct of trade with distant lands then growing in volume.

In the limited role assigned to patents by the Statute of Monopolies, they flourished with the progress of the Industrial Revolution. The basic new inventions of that period gave a strong impetus to research, and from that time forward patent control of industrial technology formed a vital and universally accepted part of the economic scene. The vast increase in production potential which these inventions brought, and the improvements in transportation and communica-

[1] For excellent accounts of the early history of patents, see, William Hyde Price, "The English Patents of Monopoly," particularly at 3-46 (1906), and George Unwin, "The Gilds and Companies of London," 293-319 (1908).

[2] See the two famous cases of *Darcy* v. *Allein*, 77 English Reports 1260 (King's Bench, 1602), and *The Clothworkers of Ipswich*, 1 Alde. P.C. 6 (King's Bench, 1614); and discussion in William C. Robinson, "The Law of Patents," at 9-12 (1890).

[3] See Price, op. cit. supra note 1, at 36; George Unwin, "Industrial Organization In The Sixteenth and Seventeenth Centuries," ch. V (1904); and William Cunningham, "The Growth of English Industry and Commerce: Vol. II; The Mercantile System" (6th ed. 1925-29).

tion which followed, unloosed strong pressures for free access to the new opportunities which were then opening up. And the period between the middle of the 18th century and the middle of the 19th century saw the rise of a competitive economic system and the development of a social philosophy to support it.[4] But the grant of patents for inventions won the firm support of many of those who shaped the thought of the times in favor of unhampered freedom of enterprise.[5]

In our own country the history of patents followed closely that in England. During the colonial period capital was scarce and enterprise extremely hazardous, and patents were granted, though infrequently, for new industries based on known technology as well as for new inventions.[6] The attitude toward patents was colored, however, by their abuse in the hands of the Crown. There was little discussion of the patent question in the Constitutional Convention. But a proposal for the adoption of a patent system received unanimous support,[7] and it was provided in article I, section 8 of the Constitution that Congress should have power—

> * * * to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.

In the early years of our national history the need for skilled artisans was great. We were in the same position in which England had been two centuries earlier. There was a particular desire to secure knowledge of the new technological developments then taking place in England. This was difficult because export of the new machines was closely controlled as was information concerning the inventions themselves. Those who succeeded in leaving with essential drawings, or who could duplicate these machines from their own knowledge, found a profitable market for their information in this country. There were suggestions that the Government should provide bounties to encourage the immigration of these men, and tariffs to protect the industries which they built up.[8] And Washington in his first inaugural address urged "the expediency of giving effectual encouragement, as well to the introduction of new and useful inventions from abroad as to the exertion of skill and genius at home." But our patent system, following the pattern of the Statute of Monopolies, limited these grants strictly.

The act of 1790,[9] which established in all essentials (except examination procedure which was not added till 1836) our patent system

[4] See, for example, Paul J. Mantoux, "The Industrial Revolution in the Eighteenth Century" (Rev. ed. 1947); Eli F. Heckscher, "Mercantilism," 2 vols. (1935); and Heckscher, "Mercantilism," Econ. Hist. Rev., 44–54 (1936).

[5] See, for example, Jeremy Bentham, "The Rationale of Reward," at 92 (1825); and John Stuart Mill, "Principles of Political Economy," book V, ch. X (1848).

[6] See, for example, Victor S. Clark, "History of Manufactures in the United States," vol. I, 1607–1860 (1929).

[7] See Walton Hamilton, "Patents and Free Enterprise," TNEC Monograph No. 31, at 23–27 (1941).

[8] See, for example, Alexander Hamilton, "Report on Manufactures," (1791), particularly at 42–43 and 60–62, as reprinted in S. Doc. No. 172, 63d Cong., 1st sess. (1913).

[9] Compare B. E. Lanham and J. Leibowitz, "Classification, Searching, and Mechanization in the U.S. Patent Office," 40 Jour. Pat. Off. Soc'y 86–87 (1958), which describes these early laws as follows:

"The 1790 act required as a condition precedent to the grant of a patent that satisfactory evidence of novelty, utility, and invention be established, which requirements are in existence at the present time. A 'prior art search' was thus necessary, and since it was apparently limited to the relatively few patents issued by American Colonies and States as well as among books on mechanics and industrial arts, no need for classification of the searchable material was then necessary.

"The first U.S. patent was issued on July 31, 1790, and the total was 57 on February 21, 1793, when a new Patent Act replaced the earlier one. The new act substituted a 'registration' system for the 'examination' system, and that unfortunate replacement continued until the act of July 4, 1836, was passed."

as we know it today, provided that, upon petition, any person could secure the grant of a patent, but only if he had—

> * * * invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used * * * [which was deemed] * * * sufficiently useful and important * * *.

The powers conferred under patents were to comprise—

> * * * the sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery * * *.

And no express obligations concerning use or licensing were imposed beyond the requirement of disclosure:

> * * * so particular * * * as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other persons skilled in the art or manufacture * * * to make, construct or use the same, to the end that the public may have the full benefit thereof, after the expiration of the patent term * * *.

The grant of patents even for new inventions was not, however, without opposition. Madison, in 1788, raised the question whether it might not be wise to reserve the right to abolish patent grants at a price.[10] And Jefferson challenged the claims that these grants were supported in natural law, which at that time was looked to as the foundation for all forms of property right:

> If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it * * *. Inventions cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done according to the will and convenience of the society, without claim or complaint from anybody.[11]

When he had gained experience in the administration of the patent statutes, however, Jefferson came eventually to favor the grant of patents for inventions.

Two principal factors account for our adoption of a patent system at a time when public distaste of monopoly was strong. An inventor's right to retain his discoveries in secrecy was generally acknowledged to be supportable in natural law.[12] At the same time, the public dis-

[10] See "5 The Writings of James Madison," at 274 (Hunt ed. 1900–1910).

[11] Letter of Aug. 13, 1813, reproduced in "The Writings of Thomas Jefferson," vol. 13 at 333–334 (Mem. ed., 1904).

[12] William Robinson, op. cit. supra note 2, at 38. As Mill stated "* * * I have seen with real alarm several recent attempts * * * to impugn the principle of patents * * * which, if practically successful, would enthrone free stealing under the prostituted name of free trade, and make the men of brains, still more than at present, the needy retainers and dependents of the men of money bags." J. S. Mill, "Principles of Political Economy," book V, ch. X, p. 549 (5th London ed., 1877).

closure of inventions was thought of as socially beneficial. Through disclosure, duplication of inventive effort could be reduced, there would be inspiration for new lines of research, and when the patent expired all might use the invention freely. It had been established at common law that these benefits of disclosure could justify the public in granting patents, and the same view took hold in this country.[13]

The other consideration which served as the basis for our patent system is summed up in the Constitution: "to promote the progress of science and useful arts." In a sense, this is the more fundamental thought, since it implies a continuing need to confer unusual private powers in order to foster invention. While the rationale of our patent system was not fully developed at the time of its founding, the essential factors which constitute its economic and social justification have not changed. What has changed is the precise form best suited to our present needs. Before undertaking a detailed examination of experience under our patent system, it will be helpful to indicate in general terms the economic and social considerations by which its performance must be judged.

B. ECONOMIC AND SOCIAL CONSIDERATIONS

It is clear that the patent monopoly has from the beginning occupied a unique role in our system of private enterprise. In other fields of endeavor, we have relied for the satisfaction of our wants either on competition or on regulated monopoly. Patents are the sole instance of publicly conferred, yet virtually unregulated, private powers of exclusion. This distinctive phase of our public policy reflects essentially the fugitive character of inventions, which makes their private control difficult; and the absence of natural tendencies toward monopoly, which makes their close public control unwarranted.

Inventors confront problems in their efforts to derive personal benefits from their labors which differ materially from those which face other producers. Other producers can effectively control the use and disposition of their products through mere possession, and additional supplies will be costly to reproduce. Inventions, however, consist only of ideas which rivals can often acquire without cost to themselves, perhaps through simple inspection of a marketed product. Where this occurs, no one will be under any constraint to take invention costs into account in setting production rates or selling prices of products which embody or utilize the invention. As a result, output and prices will fail to reflect invention costs, and no one will be able to gain a return for the effort which has gone into the invention. To put the thought another way: the "supply" of an invention, once conceived, is difficult to control, and ordinarily can be expanded at negligible cost and without pertinent limit. By contrast, the supply of other products can readily be limited, and their prices are much more responsive to their costs. This difference in supply conditions, which stems from the fugitive nature of inventions, lies at the heart of the distinc-

[13] William Robinson, op. cit. supra note 2, at 58-66.

tive treatment which inventions have been accorded in our public policy.[14]

The problem of public policy is to determine the desired supply of new inventions, and the safeguards to inventive effort which must be erected in order to insure that supply. A limited number of new inventions is assured to society even without any special stimulus. Accident or observation unrelated to deliberate inventive effort will provide some inventions. Others will be produced by those with an "instinctive bent" for invention, or who find sufficient reward in the joy of the effort or the satisfaction of accomplishment.[15] Purely economic factors will also support some inventive effort without assured safeguards. Where changes take place in the relative prices or availability of labor, materials, or capital, it may become profitable for business firms to undertake adaptations not requiring costly research, designed to economize the scarce or costly factor or utilize more effectively the plentiful or cheap factor.[16] The obsolescence of existing equipment may spur a search for means to reduce losses. And the competitive advantages which lie in market priority, or the hope of at least temporary secrecy, may lead to a degree of inventive effort.

By any social test, however, the community's needs for new industrial technology are unlikely to be satisfied through such incidental efforts or incentives. If, in determining adequacy of supply, we apply to inventions the same test that we do to most other products under our free enterprise system, we will measure performance according to cost-price relationships. By this standard, it will be in society's interest to assure, as a minimum, the supply of any invention whose costs of creation can be recovered through savings made possible in manufacture, or through the profitable sale of a new product. So long as the hazard remains that the profit potentialities of inventive effort may be dissipated through competitive use of the invention, this social aim cannot be achieved.[17] For some with inventive skill will be attracted to this work only if their prospective incomes appear as great as in other fields open to them; while others will be more likely to direct their inventive activities to the satisfaction of social needs if they can see in this manner a way of increasing their incomes.[18]

[14] Fritz Machlup contends that the difference between material and intangible goods has "nothing to do with the problem" of Government intervention to support the private value of inventions. Machlup, "An Economic Review of the Patent System," Senate Patent Study No. 15, at p. 58 (1958). It is his view that: "What really matters is the difference between 'variable' and 'sunk' costs." "Sunk" costs, however, are common to nearly all industrial and commercial ventures. Where inventions differ from most other forms of production is precisely in their intangible nature. It is because of this fact that in the short period the price-determining, variable costs of expanding supply are negligible, and in the long period there is no fixed investment ("sunk" cost) which requires replacement. These conditions do not prevail where "sunk" costs are embodied in tangible instruments of production, which are subject to attrition through use, are costly to reproduce, and the output of which is inherently limited and can easily be controlled. Professor Machlup appears to acknowledge these points in the illustrations which he himself refers to as "unrealistic," cited by him at p. 59 of his study.

[15] See Joseph Rossman, "The Psychology of the Inventor" (1931); S. C. Gilfillan, "The Sociology of Invention" (1935); and A. P. Usher, "A History of Mechanical Inventions" (1929, rev. ed. 1954).

[16] See J. R. Hicks, "Theory of Wages," at 121–130 (New York 1948); A. C. Pigou, "Economics of Welfare," at 412, 671–680 (4th ed. 1952); essay on "Invention", in Sir Josiah Stamp, "Some Economic Factors in Modern Life" (1929); and Hugh Dalton, "Some Aspects of the Inequality of Incomes" (1920).

[17] Professor Machlup contends that because of a "Headstart" inventors can make "some money" without patent protection. Senate Patent Study No. 15, supra note 14, at 59–60. He does not indicate, however, whether he believes this incentive would suffice to supply society with all the inventions whose social costs could be justified by their social usefulness. Indeed, he seems to despair of ever solving this problem, despite the fact that he deems it possible to determine the direction of socially desirable reforms (p. 80).

[18] See F. W. Taussig, "Inventors and Money-Makers" (1915); and Arnold Plant, "Economic Theory Concerning Patents for Inventions," (N.S.) Economica 30–51 (1934).

One caution must be expressed in applying this social test to inventions. It is valid only where conditions of demand and supply are in some degree competitive; or, if any significant degree of monopoly prevails, only where this control is subjected to some form of public regulation. In the course of this report, and in Economic Report No. 2,[19] we shall suggest limitations over the use of patents designed to achieve the maximum degree of competition, both in the provision and use of inventions, consistent with the social purposes of our patent system.

With these thoughts in mind, we may now examine the way in which a patent system works to provide a supply of new inventions, and its limitations as shown through experience. A patent conveys to an individual the power of exclusion over the use of an invention. With this power in hand the patentee is able to limit the commercial use of his invention, and so to preempt some part of the market value of products manufactured with its aid. Unavoidably, the use of other forms of capital, and of labor and materials, will be affected by this power of exclusion, because inventions make their contribution to social progress through improved effectiveness in the use of these other factors of production.

From the social point of view, patents are not an ideal means of encouraging inventive effort. They may come into the hands of firms which, technically, are less advantageously equipped than their competitors to use the invention. The patentee may have investments in competing technology or in competing lines of manufacture which make it temporarily unprofitable for him to employ an invention which his competitors would exploit immediately.[20] More fundamentally, patentees, since they enjoy a degree of monopoly power, are unlikely to exploit inventions to the extent warranted by their usefulness to society, and may be overcompensated in terms of their costs.[21] Production by any monopolist is likely to be at a lower level, and his prices higher, than would prevail if the industry were competitive. Moreover, the production policies of a monopolist are likely to leave some opportunities unexploited, thus forcing other productive resources into socially less useful lines of manufacture, or to work with inferior technology.

The actual strength of the monopoly represented by a patent, it should be said, is limited by the competing technology accessible to rival firms. A patent is granted on a technical and not a market basis. That is, the grant is for a scientific achievement, and the monopoly is confined to the advance made over the prior art. While the patentee is protected against "equivalents," this protection also is judged on a technical basis. Thus, marketwise, there may be close competition between patented inventions, or with unpatented technology. Insofar as this is true, the monopoly of an individual invention is socially of less consequence.

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[19] "Patent Abuse—A Plan for Its Control" to be published at a future time.

[20] See Hicks, and Pigou, op. cit. supra note 16. The owner of several competing patents may even be able to survive competitively if he shifts from the use of a better to a poorer invention.

[21] However, even under the protection of a patent an inventor may be unable to recover the full social value of his invention, because of his inability to share in the benefits he creates for other inventors, or in the economies made possible in other lines of manufacture or distribution. See Pigou, op. cit. supra note 16, at 183-185.

The precise degree of monopoly power which should be assured under patents, in order to secure a socially adequate supply of new technology and products, is difficult to judge. Inventive activity takes place under conditions of greater uncertainty than are found in most lines of production, since inventors cannot know beforehand either the effort required to reach a successful result, or the prospective commercial value of the outcome. This risk may attract those who prefer a gamble over a sure thing, even though the prospect of loss may be greatly out of proportion to the prospect of gain.[22] Others, however, may require the hope of high reward, if their reluctance to undertake such risks is to be overcome. The exact effects of patents are not predictable. High profits on successful inventions may draw so many to inventive activity that returns generally will fall below those in less hazardous enterprise,[23] with a consequent misdirection of productive resources. The high returns occasionally experienced, however, may do no more than generate self-limiting competition which provides a supply of inventions while holding profits generally in check.[24]

Despite these hazards and limitations of a patent system, the choice of means to foster invention remains a matter of alternatives. The other choices—publicly conducted or publicly subsidized research—appear less satisfactory. Apart from the inventions designed directly to satisfy public needs,[25] the production requirements of private industry and private consumer wants constitute the proper guides to inventive effort. Where demands are private, a more vigorous and sensitive adaptation to need is more likely through private incentives than through direct public provision.[26] There are, of course, fields of scientific inquiry guided neither by commercial nor public considerations, but to the support of such research a patent system has little to contribute.

The support of invention through public subsidy would entail serious administrative difficulties. If the subsidy were indiscriminate, no correspondence could be achieved between public outlays and public benefits. Yet, if the reward were fashioned according to some standard of value, there would be need to rely on experience to determine worth; and if worth of the invention were measured by actual market realization, it would vary with the extent of promotion and the rates set for competing inventions.[27] Compensation could be

[22] See Alfred Marshall, "Principles of Economics," at 400 (8th ed. 1936); and Adam Smith, "Wealth of Nations," book I, ch. X (1776).

[23] See Frank Knight, "Risk, Uncertainty and Profit" (1921).

[24] See Merton, "Fluctuations in the Rate of Industrial Invention," 49 Quarterly Journal of Economics 454–474 (1935); Simon Kuznets, "Secular Movements in Production and Prices" (1930); and Edward H. Chamberlin, "The Theory of Monopolistic Competition," at 57–64 (5th ed. 1946).

[25] J. K. Galbraith in "The Affluent Society" (1958), particularly ch. XIX, argues persuasively for expanded research supported by public funds where the results cannot be specialized to or sustained by any marketable product. While views may differ on the extent or forms of public needs for new inventions, any deficiencies which may exist in the public sector will probably call for corrective measures different from those which would apply to the private sector. Nor is it likely that reform of the patent system, which operates essentially by influencing private incentives, will prove the most effective means of meeting deficiencies in the public sector. Direct procurement or subsidy appear most appropriate where the need to be served is public rather than private.

[26] For an analysis of the considerations which make this very likely to be true in the case of inventions see Pigou, op. cit. supra note 16, at 396–401.

[27] For an early analysis of some of these problems, see John Stuart Mill, "Principles of Political Economy," book V, ch. X (1848).

confined to inventions determined to be of unusual value to the community. However, if this were done, those who failed to secure governmental compensation would be without a source of return. These uncertainties of reward, it seems certain, would materially retard the flow of new inventions.

C. RECOMMENDATION NO. E–1

It may be concluded that a patent system in some form is the most practicable means under a system of private enterprise to provide a socially adequate supply of new industrial technology. In its present form, our patent system is not wholly satisfactory for this purpose. Its weaknesses and limitations will be described in greater detail in later chapters of this report and in Economic Report No. 2. Before proceeding to that task, we shall undertake in the next chapter to define the essentials of a sound patent system.

CHAPTER II

THE ESSENTIALS OF A SOUND PATENT SYSTEM

The more extreme advocates of the patent system have credited it with a large share of our economic and technical progress. Its severest critics, citing evidence of abuse, have marked it a failure. There is a measure of truth in both views, but in the present analysis no effort will be made to appraise the gains and losses we have experienced under our patent system. Our concern will be the limitations and defects of the patent system and the measures of reform likely to produce a socially more satisfactory result, on the presumption that a patent system in some form will serve a useful purpose. There are certain ideal standards which may guide this appraisal, and these will be outlined later in this chapter. Since others judge the patent system by different standards, however, certain of the more common of these opposing views are briefly discussed.

A. SOME POPULAR MISCONCEPTIONS

1. The restrictive effects of patents are regarded by some as a virtue. They point to the inventive effort and the industrial diversification stimulated by the inaccessibility of patented technology to competitors as a social gain. By this standard, there would be almost no limit to the fragmentation of industry into isolated monopolies, and mere innovation would take its place alongside the test of inventive contribution which we now apply as a proper basis for the grant of patents. Governmental license, and not private enterprise, would then chiefly determine the use of the Nation's productive resources throughout the economy.

It is the search for new technology undertaken in anticipation of patents, and not the search impelled by limitations over the use of known technology, that the patent system is properly designed to foster. Society could, in fact, afford a greater volume of inventive effort if a way could be found to encourage inventions without according powers to limit their use. For these powers, far from benefiting society, constitute a social cost of the patent system, since they diminish output by inhibiting the use of the best technology. It may be found desirable to grant such powers as the most practicable means of fostering invention, but if so they must be carefully limited according to that need. And that need is itself limited because of the competing demands for the use of the Nation's scarce resources. It is only because commitments made under the patent system must be honored, if that incentive is to prove effective in fostering invention, that any publicly conferred powers over the use of known technology are socially justified.

2. Even those who hold a more positive view of the functions of a patent system sometimes argue that it is useful as a means of preserving competition, particularly the competitive position of small-

scale enterprise. This surely is a perversion of the concept of competition. Society's essential safeguard for the best use of its resources under a competitive system lies in the freedom it insures to serve market demands. Limitations over that freedom, with few exceptions, impair the effective performance of competition. While limitations over the size of individual firms may at certain points perhaps enliven competition, measures designed to shelter existing firms of any size can only obstruct the operation of competitive forces. In any event, patents cannot effectively serve this purpose. If there is any bias in the patent system, it is, as we shall see, in favor of the larger firms. At best, only a limited number of smaller firms are likely to be protected by this means.

3. Some regard patents as designed chiefly to encourage independent, rather than group, inventive effort. They view corporate research as confined to "routine contributions," as contrasted with the "inventive genius" which often characterizes the work of independent inventors.[28]

There is evidence that corporate research is directed principally to the development of improvements and the perfection of known inventions for commercial use.[29] Such research is not, however, socially less useful than that which may be regarded as more fundamental; nor does it stand less in need of support through patents. Like the work of inventive geniuses, it requires prolonged and systematic study by experts, and is clearly beyond the probability of ready conception by skilled artisans.[30] While, as we pointed out in the preceding chapter, a certain volume of corporate research will be supported by the desire to avert the obsolescence of specialized production facilities, a business firm cannot ordinarily afford to spend money on research if its competitors will have free and immediate access to the results. The work of inventive geniuses is much more likely to be spontaneous. Moreover, the adaptation of inventions for commercial use is vital if the public is to benefit fully from scientific progress.

4. The view of the patent system which differs most fundamentally from the standards we shall suggest looks upon patents as essential to the commercial exploitation of new inventions, principally because of the uncertainties which prevail where new products are to be marketed. It is true that monopoly powers, such as those conferred under patents, do improve the chance of high profits and diminish the risk of low profits, thus making it more attractive to hazard investment where market prospects are uncertain. More is required, however, to establish the social need for monopoly to exploit as well as foster inventions.

We have, under our private enterprise system, limited entry in the "public utilities." In those industries, the conditions of supply make competition insupportable, and monopoly powers have been both granted and regulated in order to insure adequate service to the public. (For further discussion see ch. IV.) No such general justification for monopoly holds true in the exploitation of patented inventions. Nor

[28] See *Potts* v. *Coe*, 140 F. 2d 470 (D.C. Cir. 1944); and Walton Hamilton, "Patents and Free Enterprise," TNEC Monograph No. 31, at 155–156 (1941).

[29] For a summary of TNEC testimony to this effect, see William B. Bennett, "The American Patent System," at 182–188 (1943). See also, Frank J. Kottke, "Electrical Technology and the Public Interest" (1944).

[30] For an analysis of the similarity of the inventive processes under individual and group research, see A. P. Usher, "A History of Mechanical Inventions," at 21–22 (1929).

are the market uncertainties which prevail in exploiting patented inventions unique. In fact, many patents are for improved means of manufacturing known products or for improved forms of such products.

There is, however, a more fundamental objection to the grant of monopoly powers specifically to aid in the exploitation of patented inventions. Where market prospects are uncertain, caution in the use of the Nation's resources serves a social purpose. And it cannot be demonstrated that society will benefit by according to patented inventions a generally preferred status in the use of these resources. In any event, where the only bar to entry in an industry is uncertainty of demand, rather than conditions of supply such as in the "public utilities," monopoly is not necessary to sustain production once undertaken.

In supporting the argument for monopoly to insure the exploitation of patented inventions, a great deal of stress has been laid on the costs which the pioneering firm will have to bear which its rivals will be spared, thus producing a constraint against initial market development. The problem differs according to the stage of exploitation.

During the pilot plant stage, the knowledge acquired takes such forms as records of tests and experiments, the production of models and samples, blueprints, plans for plant organization and layout, and other results of a similar nature. Such information is closely akin to patentable inventions in the sense that acquisition by competitors may be costless and accordingly requires protection to assure its supply. However, it is not usually difficult to keep such information secret. In fact, even where licenses are granted under a patent, it is often difficult to transmit to the licensee sufficient know-how to assure effective operation under the invention.

The second stage, which consists of the erection of production facilities, entails expenditures which any rival will have to duplicate. An extended market for such facilities may produce so-called external economies which will lower costs, but these conditions prevail in many industries other than those which operate under patent protection, and are unlikely to be sufficiently significant or progressive to justify the grant of monopoly powers for initial market development.

The third stage, commercialization, entails market development expenditures such as advertising, salesmen's salaries, transportation, and warehousing. It is said that the benefits of market development are shared by those who follow in the paths broken by the innovator. Per unit costs of sales are likely to be greater at an early stage than after market acceptance of a new product has been attained. Competitors, however, will not always benefit from the market development activities of their rivals, since such activities often attach trade to a single seller,[31] and may in fact create an obstacle to entry by competitors. The advantages which do fall to latecomers as a result of the general demand for a product created by the pioneering firm are not, moreover, confined to patent-protected industries, nor are they likely to be important enough to warrant the grant of monopoly powers for the mere task of initial market development.

[31] See Edward H. Chamberlin, "The Theory of Monopolistic Competition" (5th ed. 1946); and Joan Robinson, "The Economics of Imperfect Competition" (1933).

5. Patents are sometimes compared to tariffs and supported on the ground that they also safeguard infant industries. The analogy is not entirely apt. While tariffs are publicly administered, patent powers are privately exercised. Moreover, while tariffs have a clearly national orientation in the sense that they are designed to protect domestic production, patents which convey powers over domestic markets may be granted to foreign nationals who will then be free to supply such markets entirely through exports of foreign production. For these reasons, patents cannot effectively serve the public purpose of sheltering domestic industries.

B. SOME SUGGESTED STANDARDS

Over the years, many proposals have been advanced for reform of the patent system. In the chapters to follow, and in Economic Report No. 2, we shall examine some of these proposals and suggest a plan of our own. To provide a point of reference by which to fashion and appraise these measures of reform, two ideal standards are applied throughout the discussion. Certain of these thoughts will be evident from the preceding analysis; others will be more fully developed later.

1. *If a patent system is to work to best advantage socially, grants will be made only where they are required to secure the invention or its disclosure.* The free discretion to undertake industrial and commercial ventures, and to retain the fruits of those labors, are two of the most basic incentives upon which society relies under a private enterprise system to attain the best use of its resources. There is a presumption, under such a system, against any impairment of these incentives unless a clear showing can be made of social benefit. Patents operate both to limit entry in industry and commerce, and to deny to subsequent inventors the use of their own discoveries. In terms of the ideal suggested, no grants would therefore be made where the costs of the invention were nominal, or where the invention could be used competitively at a fair profit.

No patent system at present follows this ideal. All base the grant of patents on the technical achievement of the inventor, and not the need for monopoly to assure supply of the invention or its disclosure. Under our system the principal requirements for a patent are novelty in the invention, utility, and a degree of inventiveness exceeding that readily apparent to those skilled in the art.

In practical operation, the standards actually followed are likely to produce results not greatly different from those suggested as ideal, and they are far easier to administer. By confining patents to important technical contributions, the grants are likely to be made chiefly where costly experimentation has been undertaken which could not be supported without a means of safeguarding the commercial value of the results. The high rewards for inspired work, or for sheer good fortune, may perhaps be justified, as pointed out in the preceding chapter, as a means of overcoming the reluctance to undertake the hazards of inventive activity which are by their very nature unpredictable.[32]

Basing the patent on "inventive contribution" limits its application to the stimulation of invention and prevents its use broadly as a means of fostering production. This limitation appears proper. Investments made in the exploitation of inventions (new or old) do not have

[32] For further discussion, see ch. III.

the fugitive character of those made in the inventions themselves. Nor are the risks encountered in exploiting an invention likely to be as great as those in producing it, since costs and yields are subject to less uncertainty.

The grant of but a single patent for an invention appears unavoidable under any system. In any other circumstance, competition among the patentees would destroy the commercial value of the grant for the reasons cited in the preceding chapter. The grant of the patent to the first inventor has the further advantage of accelerating the perfection of the invention and its disclosure through commercial use or the application for a patent.[33]

2. *A second ideal in fashioning a patent system is to limit the powers conferred so as to confine the patentee's reward to the recovery of costs within the bounds of the social value of the invention, and to insure, insofar as compatible with the objectives sought, that production and sale under patented inventions are competitive.* In considering the costs which should properly be recoverable under a patent, account will have to be taken of the unsuccessful experiments which precede the final successful result. It is not true, as some have urged, that returns under patents should be kept high enough to meet the costs of all unsuccessful experiments, for to do so would impair the incentive to careful direction of inventive effort. But the costs of some failures are no doubt properly ascribable to the inventions actually patented.

Since under a patent the inventor depends for his return on commercial use of his invention, his reward is likely to be proportioned in some degree according to its social value.[34] The exact degree of correspondence may vary greatly, however, depending upon the limitations over output imposed by the patentee. The extent of these limitations will be conditioned by the degree of competition which prevails with other forms of technology, patented or unpatented.[35]

Two factors are counted upon under our patent system to limit the returns to inventors and to insure competitive use of the inventions: the freedom to invent and use substitutes, bolstered by the disclosure requirement; and the limited life of the grant. The purpose in conveying powers of exclusion under patents is to enable the inventor to reap the benefits of the specific invention covered by the grant, and not to provide effective control of the market; the "equivalents" covered are also determined according to technical, and not market, considerations. New inventions to provide effective market competition with the old are, in fact, encouraged through the disclosure

[33] Professor Machlup questions the theory that patent protection is exchanged for the disclosure of secrets. Senate Patent Study No. 15, supra note 14, at 52–53 and 76–77. While in his initial discussion he appears to be considering only one of the purposes of disclosure—to assure workable specifications at the expiration of the grant, he does later consider the usefulness of disclosure as a means of stimulating further research and avoiding the duplication of inventive effort. His rejection of the "disclosure" theory is founded on the judgment that "inventions probably are patented only when the inventor or user fears that others would soon find out his secret or independently come upon the same idea." It is not at all clear, however, that this fear can be equated with actual independent achievement or discovery. Professor Machlup's suggestion that comparable dissemination of technical knowledge could be achieved by special agencies in the absence of patents is meaningful only if it can be assumed that patents are rarely sought where there is any real likelihood that the invention would otherwise remain secret. This is an assumption of doubtful validity. It is the uncertainty of competition which confronts new inventors, and the added protection against this uncertainty provided by patents, that leads them to seek this safeguard. In these circumstances, the assumption would more probably have to be the opposite of that made by Machlup. In any event, the duration of the patent grant is not necessarily at issue here, as Machlup seems to suggest, since patents are designed to foster invention as well as disclosure.

[34] For an oft-quoted statement of this defense for patents, see Jeremy Bentham, "The Rationale of Reward," at 92 (1825).

[35] Professor Machlup challenges the view that any proportionality, or even approximate proportionality, can possibly be shown between the "rewards" of inventors and the "social usefulness" of inventions. Senate Patent Study No. 15, supra note 14, at p. 54. However, he bases this judgment on the timing of inventions in relation to the appearance or creation of public demand, largely subjective views of what is "trivial," and on a prediction that the socially most important inventions would not be allowed to be monopolistically exploited through patents. These considerations are, at most, limited in their applicability to the issue.

requirement. The results of inventive effort are, however, highly uncertain, and it is unlikely that close substitutes will always be found. Moreover, the concentration of patent control may impair the competitive effectiveness of new inventions.

Nor is limited duration of the patent grant a sensitive device for proportioning the returns under patents to the costs of the invention. These costs vary greatly from invention to invention, and they differ markedly in the rate at which they can be amortized irrespective of the skill and energy of exploitation. The period of the patent grant was initially based on considerations which now have little meaning. In the beginning, following the English pattern, we granted patents for a 14-year term. This term was selected by the English at a time when manufacture was in the handicraft stage and when "new inventions" were largely synonymous with wider dissemination of known skills. The aim was to secure the teaching of these skills, and patentees were protected against competition for the period during which they could train two new sets of apprentices. Little attention was given at that time to patents as a means of encouraging inventive effort. Later, as machine and chemical technology grew to importance, the emphasis shifted to fostering new inventions, and written disclosure requirements were added. In our own country, a 7-year renewal period was added in 1836; and in 1861 this was dropped and the period extended to 17 years, as a compromise with pressures for a 20-year term in lieu of the 7-year renewal.

There have been suggestions for varying the duration of patents, and even the monopoly powers conferred, according to whether the inventions are "major" or "minor." [36] Difficulties are likely to be encountered, however, if these distinctions are to be based on scientific and technical standards such as those now employed in Patent Office examinations. While there may be a rough correspondence between the social merit and technical excellence of inventions generally, and between their costs and scientific importance, these relationships are less likely to hold true for individual inventions. Administration of a "major-minor" patent system is therefore likely to prove troublesome, in terms of the ideals suggested above.[37]

It shall be the principal thesis of the remaining chapters of this report, and of Economic Report No. 2, that the most effective and practicable means of attaining the ideals of a sound patent system are to place limits on the concentration of patent control, and to outlaw certain types of restrictive provisions sometimes found in patent licenses and assignments. The positive suggestions for patent reform are presented in Economic Report No. 2. In the remaining chapters of this report, we shall examine the factors which influence the concentration of patent control, and consider the wisdom of general compulsory licensing of patented inventions.

[36] See, for example, the recommendations of the Science Advisory Board, reproduced in TNEC hearings, "Investigation of Concentration of Economic Power," pt. 3, at 1144 (1939).

[37] Professor Machlup applies the techniques of economic analysis to the problem of the socially ideal duration of patent protection in the now popular game of "model" construction. Senate Patent Study No. 15, supra note 14, at pp. 66–73. As might be expected of any "model," the assumptions made determine the conclusions reached. The "model" Machlup has chosen to illustrate the technique has, it seems to me, a pessimistic bias because he treats the "supply" of research workers on a short-run basis, without allowing time for the incentives of the patent system to produce an added supply. This bias is further evident in his assumptions, also questionable as I see it, that an increase in the amount of research activity will always increase the proportion of duplicate and substitute inventions and decrease the proportion of usable inventions, and that business firms always tend to budget their research activities as a fixed proportion of sales. It is also evident in the importance he attaches to the demand for patents as a "replacement demand." Professor Machlup's treatment of accelerated capital obsolescence as a social cost of the patent system is also questionable, since existing fixed equipment will continue to be used so long as "variable" costs of production can be met, beyond which point it would be socially disadvantageous to continue its use. Carried to its logical conclusion, his standard would appear to be a counsel against scientific advance.

CHAPTER III

CONCENTRATION OF PATENT CONTROL

The requirements of a sound patent system have greatly altered since the last basic modification was made in the patent statutes more than a century ago.[38] At that time new inventions were infrequent, and they made up only a small part of the technology in use. In those circumstances, disclosure requirements and limited duration of the patent may have been sufficient to protect the public interest.

The rise of the Nation to industrial maturity has brought a profound change in the role of patents. Increases in per capita income have made it socially worth while to devote a larger part of the Nation's resources to research yielding benefits only in the future, and have provided the means to put new discoveries to commercial use. As a result, through the years, the Nation has grown more dependent for the best use of its resources upon the enterprise of patentees holding a degree of monopoly power over new technology. To an important extent, the social effectiveness of the patent system now depends on diffusion of patent ownership and the competitive use of inventions which such diffusion will bring.

Discussion of this general problem, which is closely bound up with restrictive agreements among owners of competing patents, is deferred to Economic Report No. 2 dealing with patent abuse. However, since the concentration of patent control is often unrelated to abuse, the principal factors leading to such concentration are examined here. Three considerations have been important in patent concentration: (1) the desire to diminish the risks of inventive activity; (2) the desire to provide safeguards against competing inventions; and (3) the concentration of manufacturing control.

A. TO DIMINISH RISKS OF INVENTIVE ACTIVITY

The most fundamental cause of patent concentration is the extraordinarily hazardous nature of inventive work. In all business activity there are production and market factors which cannot be appraised on a predictable basis. Inventive projects are subject to an unusually high degree of such uncertainty. There is no clear way of estimating in advance the product of inventive activity, nor the probable cost or commercial value of any discoveries which may result. For this reason, there is no reliable guide to the amount of capital and labor which may profitably be devoted to such projects. In other fields, production and marketing experience ordinarily provide a basis for more accurate estimates of probable costs and returns, and a great many of the risks are predictable.

[38] Although the patent laws were codified and revised in 1952 (Public Law 593; 35 U.S.C. secs. 1-293), and a few minor substantive changes were made, the basic structure and philosophy of the 1836 statute was retained.

There are only two ways in which the risks of inventive effort may be diminished for a particular investor, business firm, or inventor: (1) efforts or investments may be distributed over a wide field so as to improve the chance of encountering a successful result; or (2) effort or investment devoted to a given field of research may be expanded, making possible more extensive use of specialized personnel, a larger body of experience and a larger number of tries, thus improving the chance of securing an outstanding result.[39]

Whichever tactic is employed to diminish uncertainty, those who use larger amounts of capital will in the long run have an advantage. These benefits of large-scale research are likely to lead to concentration of patent control, and the latter tactic is likely to result in consolidation of competing inventions. Small investors may be able, in some degree, to overcome this disability by joining with others in employing specialized research organizations to carry on experiments for them. But it is unlikely to be wholly overcome in this way, since outside research groups ordinarily lack intimate knowledge of manufacturing problems and market prospects.[40]

Several common errors of thinking must be avoided. Concentration of patent control is often ascribed to the superior financial resources of large firms. And some observers have expressed the view that larger firms are favored in the development of inventions because the funds to support inventive activity must come from the proceeds of previously successful inventions. There is some truth in these contentions, since there is a tendency for corporate earnings to be used preferentially within the firm's own operations. However, there is a common market for capital and labor from which productive resources are drawn into various employments on the basis of anticipated profits. Projects for experimental activity have access to this general supply of capital and labor on the same basis as do other enterprises, and larger firms enjoy at best only a limited advantage in this respect.

B. TO MONOPOLIZE COMPETING INVENTIONS

Patent concentration is also sometimes the result of deliberate efforts to acquire control over competing inventions without regard to the economies of large-scale research. Because of the monopoly powers conferred under patents, business firms always stand in danger of exclusion from the market by rival patentees. A comparable hazard exists also in patent-free industries, but it can more easily be overcome where entry is not impeded by the protection of a patent. The only effective countervailing measure against patents is to anticipate the inventions of competitors or to develop acceptable

[39] For a general discussion of this problem, see Knight, op. cit, supra note 23.

[40] For discussion of cooperative and contract research, including attention to the problems of smaller business concerns in connection therewith, see: OEEC, "The Organization of Applied Research in Europe, the United States, and Canada," 3 volumes (Paris 1954); Proceedings, President's Conference on Technical and Distribution Research for the Benefit of Small Business, Washington, Sept. 23-25, 1957; Office of Technical Services (John C. Green, Director), "Technical Research Activities of Cooperative Associations," Senate Patent Study No. 21 (1958), Herner, Meyer & Co., "Research and Development and the Use of Technical Information in Small and Medium Sized Manufacturing Firms," a report to the Office of Technical Services (Washington 1956); Herner, Meyer and Ramsey, "How Smaller Firms Solve Problems and Keep Abreast of Technical Developments," prepared for the Office of Technical Services (1957); Arnold, "Why Not Try Cooperative Research?" 32 Harv. Bus. Rev. 115-22 (1954). For additional references containing discussion of the subject, see Bureau of Labor Statistics (U.S. Department of Labor), "Productivity: a Bibliography" (Washington 1957); National Science Foundation, "A Selected Bibliography of Research and Development and Its Impact on the Economy" (1958).

substitutes. While this rivalry to perfect patentable inventions may result in patent concentration, it has also a tendency to disperse patent control.

A more prolific source of patent concentration is the desire to provide protection against existing rivalry in order to improve profits. This is an objective in which all the members of an industry may join. The existence of patents simplifies industrywide controls because patentees enjoy legally enforceable monopolies in limited fields, and the competition to be confronted is thus more readily defined and more easily brought under control. Concentration of patent control arising from these pressures is likely to take the form of agreements among individual patentees, rather than centralized ownership. However, where one firm in an industry begins with a strong patent position, it may be able to prolong and extend its control.

The pressure for such agreements has increased. Where capital is growing in volume, and increased efforts are being devoted to research, the competitive position of individual firms is more seriously in danger. There is greater likelihood that new firms will be organized to manufacture known products under existing methods of production. And it is more probable that new products and new processes and machines will appear to impair or overthrow the competitive position of existing firms. Moreover, the losses through such innovations are greater where there are investments in specialized facilities such as are required to employ modern technology. The growth of markets in a spatial sense, resulting from improved means of transportation and communication, has a similar effect by expanding the sources of new competition. These hazards of competition are probably the principal, although not the sole, cause of restrictive patent agreements.

Firms with established research, manufacturing, and marketing facilities are likely to be favored in the acquisition of new inventions. They are assured of control over the output of their own research. And, where they have related inventions of their own, they may be able to bid higher than others for new inventions independently conceived. Firms already operating a plant or sales organization may be able to exploit a new invention more economically than it can be separately done; and the possession of these facilities may afford assurance of prompt exploitation of new inventions.[41]

The larger firms in an industry have a stronger incentive to acquire patents for defensive purposes than do the smaller. This is true because of the greater size of their investments which would benefit from protection against competition. The greater the investment in specialized capital, the more is the potential loss through competing products or processes. Hence the larger the financial outlay which mere defensive protection will support. Nevertheless, the primary stimulus to the development and acquisition of new inventions lies in the competitive advantages which these inventions hold. It will therefore be to the interest of any firm in the industry, large or small, or of any possessor of free capital, to develop or acquire control of the more advantageous product forms or techniques of manufacture, within the limits of the commercial value of the invention.

[41] For an analysis of how these factors have worked out in a specific industry, see Kottke, op. cit. supra note 29.

C. AS AN OUTGROWTH OF CONCENTRATION OF MANUFACTURING CONTROL

Patent concentration may also be an incidental result of industrial concentration growing out of the production and distributive economies of large-scale manufacture.[42] We cannot here examine the many considerations which have given rise to industrial mergers and consolidations, or the growth in size of individual business firms. It is sufficient to note that even where such concentration is the result wholly of cost advantages in production or distribution, it may bring integration of patent ownership as thoroughgoing as that which stems from the factors earlier discussed. It is probable that industrial integration which is horizontal (at the same stage of manufacture or distribution) will cause a more significant degree of patent concentration than vertical consolidations. Moreover, the patent concentration which results from horizontal integration is more likely to involve competing inventions.

In some degree, the cost advantages of large-scale enterprise have been the result of advances in technology. Technological progress has thus indirectly promoted patent concentration. It is probable, however, that only a limited group of patented inventions have had this effect. And there are reasons to believe that the industrial concentration which we have actually experienced may have exceeded that which rests on this ground. There can be no certainty how far future scientific progress will promote further industrial concentration.

[42] For a discussion of patents and technology as a factor in corporate mergers and acquisitions, see Murray Friedman, "The Research and Development Factor in Mergers and Acquisitions," Senate Patent Study No. 16 (1958).

CHAPTER IV

GENERAL COMPULSORY LICENSING

Both the virtues and the faults of the patent system, it will be clear from the foregoing chapters, may be traced to the monopoly powers conferred under patents. Many have seen in general compulsory licensing of patented inventions a happy escape from this dilemma.[43] Under this plan patents would continue, but patented inventions would be made available to all producers at "reasonable" royalties. The objective would be to place the use of patented inventions beyond the discretion of patentees while preserving "fair" returns for the inventors. Thus, while patentees would lose power over manufacture and commerce under their inventions, they would retain "exclusive rights" to the fruits of their discoveries. And royalties would presumably be set so as to preserve the role of patents as a stimulus to invention and disclosure.

General compulsory licensing would clearly remedy certain of the deficiencies of the patent system. It would open the most advanced technology to all producers, and so would assure larger output at lower prices (at comparable royalty rates), and greater effectiveness and better balance in the use of productive resources. There would be less danger of inventions lying idle for want of rights under collateral patents, or because of the shortsightedness or inertia of patentees or deliberate nonuse founded on the desire to protect existing investments. Independent inventors would experience a wider demand for their discoveries. Patents would cease to serve as an instrument of industrial concentration, or as a basis for industry-wide controls over manufacture and commerce. And the opportunity would be diminished for monopoly through product differentiation resting wholly on physical composition.

In practical operation, however, a system of general compulsory licensing would be likely to impair the effectiveness of patents as a stimulus to invention and disclosure. The principal problems relate to (1) the assurance of returns within the life of the patent; (2) the rate of these returns; and (3) the enforcement of the patent. The chief hazard is that general compulsory licensing would dim the prospect of returns, upon which the stimulative influence of patents depends at the inventive stage.

A. ASSURANCE OF RETURNS

The effectiveness of patents as a stimulus to invention depends on the prospect of earnings during the period of the grant. Any delay in exploitation results in a loss of earnings which cannot later be recovered when the invention becomes available to competitors.

[43] President Roosevelt suggested this approach in his message to Congress of Apr. 29, 1938, which led to the establishment of the Temporary National Economic Committee. The TNEC in its final recommendations adopted this proposal. See S. Doc. 35, 77th Cong., 1st sess., at 18, 36 (1941).

Under general compulsory licensing, patentees would be deprived of certain inducements which are now operative to accelerate the exploitation of their inventions.

The competition induced by general compulsory licensing would probably speed the immediate use of clearly profitable inventions. However, at the time research is carried on there is no way of estimating the probable appeal of any discovery. Inventors are likely to overestimate the need for exclusive rights to assure prompt exploitation. For this reason, general compulsory licensing may have an unnecessarily retarding effect on invention.

These effects are likely to be most serious where patentees are dependent upon others for the exploitation of their inventions. Where only nonexclusive licenses may be offered, as under a system of general compulsory licensing, it will not be possible for the patentee to impose more than nominal minimum royalties. Accordingly, the patentee's income will be dependent upon actual commercial use of the invention by his licensees. An exclusive licensee may also withhold the use of an invention, but in these cases the patentee may successfully require the payment of substantial minimum royalties.

General compulsory licensing may also limit opportunities for the disposal of inventions through assignment. This represents the principal means of realizing at the time of patenting the full future value of an invention. With access to inventions assured at reasonable rates, and confronted with the necessity of issuing licenses to all competitors at royalties beyond their control, business firms will have little incentive to risk capital in the purchase of patents. The reduction of this market for patented inventions is of particular concern to independent inventors.

The effects of general compulsory licensing on firms which exploit their own inventions are less clear. Since there will be assured access to inventions developed by competitors, there will be less incentive to undertake the risks of invention. And where there are already investments in one form of technology, there may be reluctance to develop competing inventions which will immediately become available to rivals. On the other hand, even under general compulsory licensing the inventing firm is likely to reach the market first under a new invention. The monopoly profits which can be gained in this way, and the long-range benefits of a reputation for preeminence, provide a strong inducement to invention. And there will always remain some incentive to invent on the basis of anticipated royalties under general compulsory licensing. Where inventions can be used effectively in secrecy, or are likely to be profitable only for a short period, general compulsory licensing may result in nonpatenting.

B. RATE OF RETURNS

At present we rely on bargaining between patentee and licensee to determine royalties. This affords an opportunity to proportion royalties somewhat in correspondence with the commercial value of individual inventions. The incentive is thus sustained to supply all inventions which offer prospect of profitable use. The right to bargain privately for the use of inventions is important if for no reason other than the fact that inventors are likely to place a high value on their own capacities to secure favorable terms.

Under general compulsory licensing, patentees would be allowed to issue licenses on privately agreed terms. But applicants would have recourse to rate determination by the Government, and the rates so fixed would be likely to control all private negotiations. In any effort publicly to fix royalties for patents, only the broadest classes of inventions could be recognized, and the rates set would have to be highly arbitrary. Inventors would be uncertain of the treatment they might receive, and the prospect would therefore be diminished for the supply of all inventions whose costs could be recovered through commercial use.

These effects can be seen more clearly by considering the problems of rate determination under general compulsory licensing. Four principal standards have been suggested for this purpose: (1) recovery of the value of the invention to the licensee; (2) recovery of the cost of the invention to the patentee; (3) compensation for damages suffered by the patentee through the competition of licensees; and (4) "conventional" or "typical" rates for the class of invention involved.

The value standard has little meaning where licenses are to be available to all applicants. Since an invention may be used at the same time by a number of producers, and since the value of an invention to any one producer depends partly on the terms offered to competitors, this standard places no floor under royalties.

The cost standard is, in principle, the most satisfactory. However, as we pointed out in chapter I, this standard would be difficult to administer. Since each invention is unique, past experience would be of little use in determining the costs of new inventions, so that these costs would have to be separately calculated. Nor does past experience aid in estimating probable royalty incomes at alternative rates for a new invention; even early demands for a new invention may fail to reflect its full future value. Thus, the margin of error in such calculations would probably be extremely great.

The damage standard is applicable only where the patentee manufactures under the invention. Where the patentee has invested in manufacture, only royalties high enough to exclude licensees will prevent losses through competition. If compensation were to be granted for losses actually experienced, account would have to be taken of investments in specialized production and distribution facilities. This would greatly complicate royalty determination.

The fourth standard is the one most commonly suggested, and is probably the most expedient and practicable, at least for a short period. This is to base royalties on "typical" rates as shown by past experience. New inventions are not always easy, however, to fit into old categories. And under general compulsory licensing the number of categories, to be workable, would have to be limited. It is doubtful whether "typical" rates can be found in many fields.[44] But even if they can, they are unlikely to reflect cost and income relationships applicable to new inventions. If general compulsory licensing should be instituted, there would no longer be an independent source for such determinations. It is questionable, finally, how far royalties set in private bargaining can serve the purposes of general compulsory licensing. Rates privately set are ordinarily designed to maximize revenue, considering the manufacturing and distributive position of

[44] A survey by the author of royalty terms in a group of patent licenses vested by the Alien Property Custodian disclosed little in the way of a uniform pattern in the fields examined.

the patentee. Since the purpose of general compulsory licensing would be to secure wider use of patented inventions insofar as this could be done without impairing the future supply of inventions, the rates set would have to be at the lowest point which would permit the recovery of costs.

It is probable that general compulsory licensing would affect the returns under different inventions in different ways. Inferior inventions now used because of the unavailability (or limited use) of the better ones would be likely to suffer reduced income. Conversely, the superior inventions, almost without regard to how royalties were set, would be likely to benefit. And dependent inventions would in all cases tend to increase in value.

C. ENFORCEMENT OF THE PATENT

General compulsory licensing may make the enforcement of a patent more difficult and more costly. With so many properly licensed manufacturers, infringement may be more difficult to isolate. And it may grow more common, since where it is detected a license will be available to assure continued operation.[45] The burden of enforcing the patent will rest solely with the patentee where there is general compulsory licensing. Nonexclusive licensees have, individually, insufficient stake in the invention to bear the cost of enforcement, and they are legally in no position to take such action. Moreover, as licensing is extended, costs of negotiation, audit, and royalty collection are likely to increase relative to royalty income, and beyond a point may exceed that income. This is a likely result of the fact that the more licensees there are the smaller are the probable sales of any one. Costs of administering the licenses are not likely to decrease proportionately, and the net income of the patentee is therefore likely to decline. How far this can be taken care of in the royalties set will vary with the worth of the individual inventions.

D. A QUESTION OF PRINCIPLE

Apart from administrative difficulties, general compulsory licensing involves also an important question of principle. Two choices are open to safeguard the public interest in the use of patented inventions. One, represented by general compulsory licensing, is to impose conditions of price and service comparable to those now applied to the "public utilities." The other is to maintain competition in the use of patented inventions through measures especially suited to the conditions of limited monopoly which prevail where patented technology is important in an industry.

The public is concerned, as we pointed out in chapters I and II, to assure the use of superior technology and to secure output under that technology at as high a level as possible considering the need to maintain a continued supply of new technology. At present we rely chiefly on the freedom to invent and to use substitutes, and on certain applications of the antitrust laws, to perform this task. The competition so preserved in some degree induces the use of the best

[45] The Swan committee in England found that in many cases the opposite occurred. Licenses were often taken because it was cheaper to do so than to challenge patent validity, with the result that invalid patents often remained unchallenged. See "Second Interim Report, Board of Trade, Patents and Designs Acts" (April 1946).

technology, limits the returns to inventors, and encourages the supply of new inventions.

Under general compulsory licensing, governmental action would supplant competition in performing these tasks. The royalties set under such licensing would determine the technology used, govern the earnings of inventors, and condition the supply of new inventions. The assumption of these responsibilities by Government may require either regulation of entry into inventive activity, authority to extend the period of monopoly to assure a proper return to inventors, or some form of public subsidy. Without these added powers, rates could not be set with any assurance of their effects on the supply and use of inventions. The choice of general compulsory licensing amounts, therefore, to a decision to deal with the problem of patent abuse through strengthening the monopolies conferred and subjecting them to close public control.

Such regulation has been resorted to in the past principally where cost conditions have made competition either unenforcible or socially wasteful, and where the product or service involved has been regarded as vital in the public interest. Where decreasing-cost conditions prevail in an industry, there is a so-called natural tendency either toward monopoly or agreement among competitors. Efforts to maintain competition in such industries are likely to prove unsuccessful; and if successful, tend only to bring prices below costs and to cause unnecessary duplication of facilities. In these circumstances, there may be reluctance to enter the industry, or ruinous competition leading to agreement among competitors. Monopoly has therefore been publicly sanctioned in these industries as a means of assuring private investment sufficient to provide adequate service, and to prevent wasteful commitments of capital. And public controls have been imposed to assure adequate service at reasonable rates. An essential part of this scheme of control has been regulation of entry on the basis of "public convenience and necessity."

The limiting principle observed in the application of public utility controls reflects a distinction which makes a real difference in a democracy. It expresses the policy that competitive private enterprise should be relied upon to secure and regulate production wherever it can adequately serve social needs. By this standard, no clear justification exists for the general compulsory licensing of patented inventions.

In the case of inventions, effective monopoly is not inevitable. A successful invention stimulates a search for substitutes. To preserve this incentive it is necessary only to confer monopoly for individual inventions and their technical equivalents. Rivalry between competing inventions has not, in a general sense, exhibited a natural tendency toward monopoly, nor are there general dangers of social waste in competition among inventions which can be substituted for one another. Except in a limited group of cases, individual inventions are not of sufficient public importance to justify a policy of general availability apart from the production undertaken by the patentee.

In view of these facts, it appears that reliance has properly been placed on competition to secure the commercial use of superior technology and to limit the returns to inventors. However, neither the antitrust laws nor the patent statutes are in their present form

adequate for the purpose of maintaining such competition. A plan to make them so is presented in Economic Report No. 2. Accordingly, in anticipation of those proposals—

E. RECOMMENDATION NO. E–2

It is recommended that no provision for general compulsory licensing be incorporated in our patent system. The arguments against general compulsory licensing, recited in this report, do not apply to the limited compulsory licensing proposed in chapters XII and XIII of Economic Report No. 2. The sanctions there recommended apply principally where there have been violations of the suggested Code of Fair Patent Contract Provisions, and in all cases the patentee is in a position to avoid the application of this remedy. Where other remedies fail to provide proper use of patented inventions, there is greater justification for resort to compulsory licensing. And where it is applied only in a limited number of cases, individual determination of royalties is more feasible: there will be a previous record of experience in the cases in which compulsory licensing is imposed, and a continuing body of privately negotiated license terms to furnish comparisons. Finally, where compulsory licensing is imposed, as suggested, after prolonged nonuse of an invention, there is less danger that the reward to the inventor will be adversely affected.

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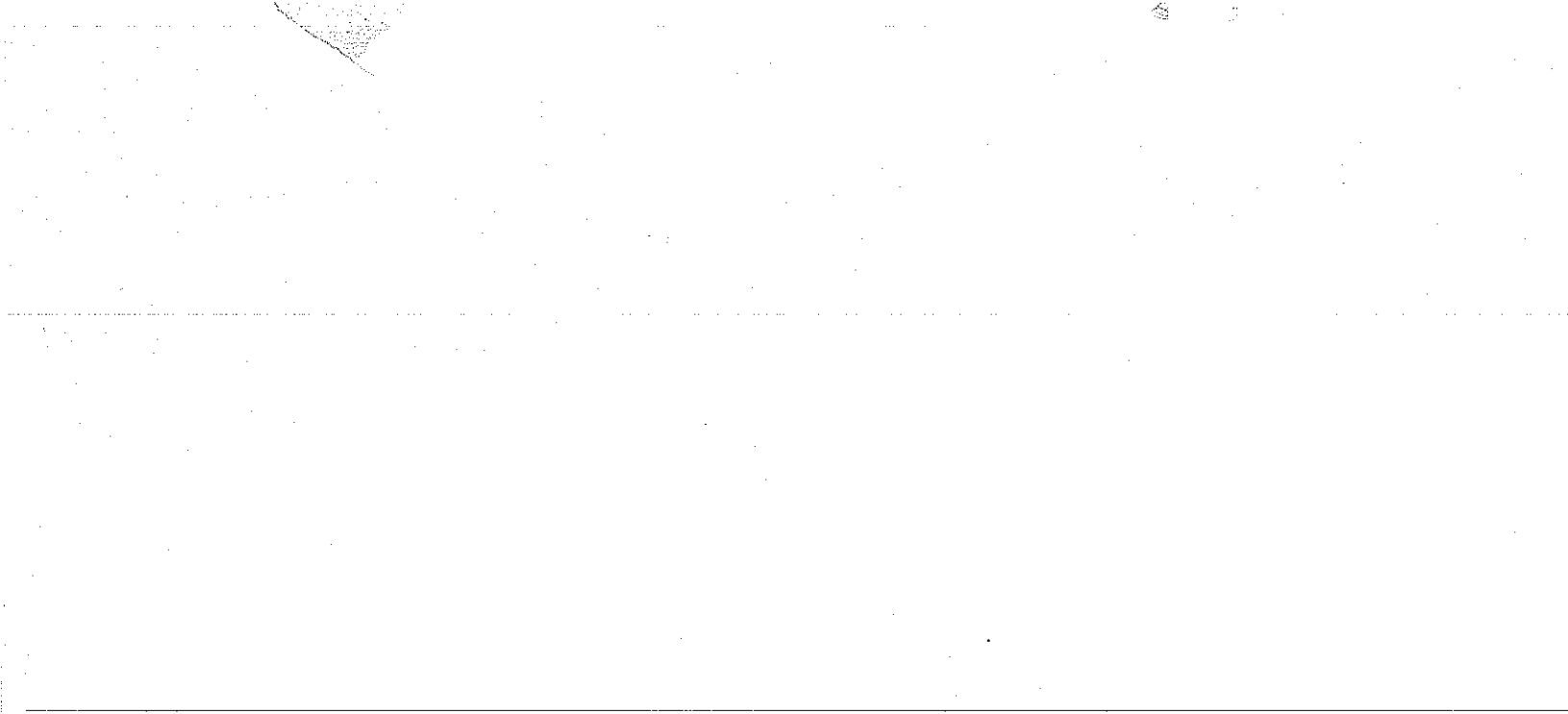

86th Congress
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AN ANALYTICAL HISTORY OF THE PATENT POLICY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STUDY OF THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS

OF THE

COMMITTEE ON THE JUDICIARY

UNITED STATES SENATE

EIGHTY-SIXTH CONGRESS, SECOND SESSION

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FOREWORD

"An Analytical History of the Patent Policy of the Department of Health, Education, and Welfare" was prepared by Miss Gladys Harrison, former Assistant General Counsel of the Department, for the Subcommittee on Patents, Trademarks and Copyrights of the Senate Committee on the Judiciary as part of its study of the U.S. patent system, conducted pursuant to Senate Resolutions 53 and 240 of the 86th Congress. The study is one of several being prepared under the supervision of John C. Stedman, associate counsel of the subcommittee.

Perhaps the most important, and certainly the most controversial, issue concerning the patent system today is the question of the respective rights of the inventor and the Government in patents resulting from Government-supported research. Among the revolutionary changes in the methods and conditions of research which have occurred in the last two decades one of the most significant is the tremendous increase in the research conducted or financed by the Federal Government. Twenty years ago the Federal Government spent $74 million for scientific research and development; today the amount is estimated to be $7.4 billion.

Approximately one-fourth of the Government-sponsored research is conducted directly by Government agency and three-fourths of it is done in nongovernmental research establishments under contract or grants. The impact of this striking development upon a patent system that was geared primarily to a private enterprise system of research is obvious. Complex and crucial policy issues arise in allocating to the inventor, his company, and the Government, the patent and other proprietary rights that flow from such research.

At the present time, there is no settled Government policy on the allocation of rights to patents resulting from Government-sponsored research. Each agency develops its own practices, guided mainly by its own judgment as to what best promotes the public interest. Among those interested in the subject the contentions and proposals are equally diverse and varied.

In recognition of the long-range importance of these issues, this subcommittee has for some time been looking into the patent practices and policies of the many Government agencies that undertake or sponsor research. Among the most important of the nondefense agencies in this respect is the Department of Health, Education, and Welfare. Consequently, the present study makes a significant contribution to our knowledge. Miss Harrison's report is especially valuable because it goes beyond the purely formal aspects of the HEW policy, tracing its historical development and examining its actual operation and effect up to the year 1960.

The author's conclusions are most interesting. On the basis of HEW experience, she finds little justification, in terms of the public interest, for leaving patent rights with the inventor, whether he be an employee,

a grantee or a contractor. She also finds patent licensing a less than satisfactory means of regulating, in the public interest, the uses of inventions covered by such patents. Finally, it is her opinion that, except in unusual circumstances, the Department is better off to rely on publication than on patenting to protect its rights in inventions and to bring them into public use. While she is careful to limit her observations to HEW, Miss Harrison's conclusions are of great significance in regard to the operation and role of the patent system generally, since they raise the important question of how far they may be equally valid for other agencies.

In publishing this study, it is important to state clearly its relation to the policies and views of this subcommittee. The views expressed by the author are entirely her own. The subcommittee welcomes the study for consideration and believes it represents a valuable contribution to patent literature. However, publication of the study in no way signifies that the subcommittee agrees with the statements contained in it.

JOSEPH C. O'MAHONEY,
Chairman, Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, U.S. Senate.

SEPTEMBER 9, 1960.

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OTHER PUBLICATIONS

Hearings, American Patent System, October 10, 11, and 12, 1955.
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Report, Patents, Trademarks, and Copyrights (S. Rept. 1202, 86th, 2d, 1960).

AN ANALYTICAL HISTORY—THE PATENT POLICY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

By Gladys A. Harrison

A. Historical Background and Development of Patent Policy

The youngest department of the Federal Government, the Department of Health, Education, and Welfare, has a three-pronged patent or invention policy. It covers inventions made by employees of the Department, inventions made in the course of research assisted by grants, and inventions made in the course of the performance of testing or research contracts. Briefly stated, the policy is one which has favored the dedication to the public of the inventive product of the research financed by the Department and which has relied increasingly on the technique of publication to that end. Still relatively new and uneven in its administration, which has been largely decentralized, the underlying concepts have gathered strength as experience has expanded, notwithstanding refinements introduced in recognition of the policies and contributions of other parties to the research effort.

Although some of its research programs antedate the creation of the Department itself, Congress has provided no statutory directive with respect to patent matters. The evolution of the Department's policy has been compelled by the very existence of the patent system in its present form, on the one hand, and the statutory objectives of Department programs on the other. As will be seen, in the process of developing the policy there has been little to indicate that the patent system could be availed of to further these objectives. On the contrary, the system is one which has had to be coped with in order that the objectives of the Department's work, and particularly the objectives of its research program, should not be thwarted or impaired. The problem is one which has consumed time and money and effort ill-spared from directly constructive activity.

The problem, moreover, is a growing one, and is one which will be increasingly shared with other agencies as their research activities expand. Some agencies, and notably those that deal in the awesome developments of atomic energy [1] and outer space,[2] are guided and fortified by special statutory directives. The Department of Agriculture, with respect to its marketing research contracts, has a mandate to make the results "available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine." [3] The Tennessee Valley Authority [4] and, more recently,

[1] 42 U.S.C. 2181–2190.
[2] Public Law 85–568; 42 U.S.C. 2457.
[3] 7 U.S.C. 427.
[4] 16 U.S.C. 831d(1).

the National Science Foundation [5] have been given charters of authority to deal with the problem in their special fields.

These provisions indicate increasing congressional awareness of the patent problem with respect to the vastly expanding areas of Federal research.[6] As yet, however, they reflect no overall determination of policy as to the extent to which the results of such research, because publicly financed, should be dedicated to the public, or otherwise reserved for its benefit, nor as to the distinctions which in this regard might be drawn between the results of research conducted for general use and enlightenment and research directed exclusively to the production of weapons or other objects required by the Government for its own use. The late Chairman of the Government Patents Board,[7] Benjamin B. Dowell, although advocating a uniform rule for all employees of the Government, has recognized that the agencies in which most inventions occur have widely different interests in the use of such inventions and fall into what he called the "procurement group" and the "public service group," defined, respectively, as follows:

> (1) those concerned primarily with the procurement of new and better items of material and equipment for their own use * * *; and (2) those concerned primarily with the development of new items and ideas that would advance the national economy and welfare which they may dedicate to the public for free use * * *.[8]

The Department of Health, Education, and Welfare belongs clearly to the "public service group." Moreover it represents a blending of traditional governmental activities and new forces which have swept away many barriers to Federal action. In facing up to the patent problem, among others, the Department has had the benefit of the experience of its various constituent organizations and the perhaps greater benefit of a fresh approach. Whether or not that approach with its deemphasis upon patents as such is sound, examination of the history of the problem in the Department may be helpful in indicating the extent to which government agencies, and particularly the civilian, having substantial research programs may be assisted in obtaining their program objectives either by special patent clauses in their own legislation or, more broadly, by modification of the patent code itself in recognition of the peculiar situation of the Government in relation to patents.

Its experience is the more significant since, aside from the Department of Defense, the Atomic Energy Commission, and the National Aeronautics and Space Administration, the Department now makes the heaviest outlays for research of any Federal agency. In the field

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[5] 42 U.S.C. 1871.

[6] See "Federal Funds for Science, VIII: The Federal Research and Development Budget, Fiscal Years 1958, 1959, and 1960," published by the National Science Foundation. The Federal obligations for research, basic and applied, in fiscal year 1959 represent an increase of 71 percent over fiscal year 1956. Ibid., p. 24.

[7] The Government Patents Board was established by Executive Order 10096, dated Jan. 23, 1950, to provide "a uniform patent policy for the Government with respect to inventions made by Government employees." The Chairman is empowered to make all decisions with finality under the order, the Board being purely advisory.

[8] See statement of the late Mr. Benjamin B. Dowell, at p. 22, hearings before Subcommittee No. 3, Committee on the Judiciary, House of Representatives, Mar. 3 and Apr. 25, 1958.

of research in the life sciences, and particularly the medical sciences, the Department easily tops the field.[9]

1. GENERAL BACKGROUND OF THE DEPARTMENT

Created by Reorganization Plan No. 1 of 1953, the Department with some changes of form and an elaboration of controls at the top administrative level, is essentially a successor to the Federal Security Agency.[10] That Agency, established in 1939, had been the assembly point for various agencies and functions derived from departments of the most varying traditions.

From the Treasury Department had come the Public Health Service, orginally known as the Marine Hospital Service, which had been organized in that Department in 1798 to administer the first Government health program, that of medical care in Government hospitals for merchant seamen,[11] and had expanded later to include, among other functions, those of foreign and interstate quarantine and biologics control. The era of great expansion into the fields of research and grants-in-aid had its beginning in the authorizing legislation of 1912. From the Treasury also the Agency derived responsibilities with respect to the American Printing House for the Blind.[12] The Food and Drug Administration, stripped of two of its functions, came to the Agency from the Department of Agriculture.[13] The Children's Bureau, leaving behind its child labor enforcement function, derived from the Department of Labor.[14] The Office of Education was transferred from the Department of the Interior by the first reorganization plan, and there were to follow St. Elizabeths Hospital, Freedmen's Hospital, and certain statutory responsibilities with respect to Howard University, and the Columbia Institution for the Deaf.[15] From the Census Bureau in the Department of Commerce came the Office of Vital Statistics.[16] The Social Security Administration in the Agency retained most of the functions of the Social Security Board under the Social Security Act of 1935.[17] The Office of Vocational Rehabilitation was created by Agency order in 1943 to carry on that function which had been in the Office of Education.

Since the establishment of the Department there have been two notable transfers by legislative enactment. The functions of the Interior Department with respect to Indian health were transferred effective July 1, 1955,[18] and the Armed Forces Medical Library, one of the largest specialized research libraries in the world, was transferred in 1956 from the Department of Defense to become a part of the National Library of Medicine in the Public Health Service.[19]

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[9] See table 13, at p. 60, "Federal Funds for Science, VIII." The table does not reflect the large increase in appropriations for the year 1960 over the budget estimates submitted to the Congress.

[10] Reorganization Plan No. 1 of 1953; 67 Stat. 203; 5 U.S.C. 133z. The Federal Security Agency was created by Reorganization Plan No. 1 of 1939, pt. 2; 5 U.S.C. 133t.

[11] Act for the Relief of Sick and Disabled Seamen, approved July 16, 1798; 1 Stat. 605.

[12] Transferred to the Federal Security Agency by Reorganization Plan No. II, effective July 1, 1939 (5 U.S.C. 133t). The same plan transferred also the radio and film service of the National Emergency Council for Administration.

[13] Reorganization Plan No. IV of 1940; 5 U.S.C. 133t.

[14] Reorganization Plan No. II of 1946; 5 U.S.C. 133y.

[15] Reorganization Plan No. IV of 1940; 5 U.S.C. 133t.

[16] Reorganization Plan No. II of 1946; 5 U.S.C. 133y.

[17] Approved Aug. 14, 1935; 49 Stat. 620.

[18] Public Law 568, 83d Cong.; 42 U.S.C. 2001–2004.

[19] Public Law 941, 84th Cong.; 42 U.S.C. 275.

Mixed as was the parentage of the agencies thus assembled, the Department was founded on a unifying concept. As stated by President Roosevelt, in sending up the first reorganization plan to the Congress, this was—

> to group * * * those agencies of the Government the major purposes of which are to promote social and economic security, educational opportunity, and the health of the citizens of the Nation.

In 1946 President Truman declared that "the time has now come to strengthen the machinery of the Federal Government for leadership in dealing with the social problems of the country." In sending up Reorganization Plan No. II of that year he made this more detailed affirmation of Agency purpose:

> Broadly stated the basic purpose of the Federal Security Agency is the conservation and development of the human resources of the Nation. Within that broad objective come the following principal functions; child care and development, education, health, social insurance, welfare (in the sense of the care of the needy and defective), and recreation (apart from the operation of parks in the public domain).

The purpose and justification of the Department were expounded by President Eisenhower in transmitting to the Congress Reorganization Plan No. 1 of 1953:

> The purpose of the plan is to improve the administration of the vital health, education, and social security functions now being carried on in the Federal Security Agency by giving them cabinet rank. Such action is demanded by the importance and magnitude of these functions which affect the well-being of millions of our citizens.

There was thus built into the structure of the Federal Government a top-ranking agency uniquely concerned with the well-being of people, not as pertaining to a particular economic class or occupation but simply as individuals. Other departments of the Government are charged with traditional functions of a national administration such as the conduct of foreign affairs, the national defense, the administration of justice, the management of the currency and the raising of revenues, the operation of the postal system, the conservation of the public land and physical resources of the Nation. Others, such as Agriculture, Commerce, and Labor, are concerned with the problems of particular segments of the population as characterized by types of economic interest. Viewed as a whole, however, the functions of the Department of Health, Education, and Welfare are the most oriented to the general welfare and are the least specialized and the least procurement minded of any of the departments of the Federal Government engaged in research activity of any magnitude.

This orientation, ever more clearly defined, of the Department to the general welfare has been matched by growing emphasis on certain types of methodology. Here there is no lack of statutory direction. The mandate to find out and discover, and (most important from the standpoint of patent policy) to share the results of study and research, runs through the statutes which are basic to most of the constituent agencies of the Department. For example, the Public Health Service Act was enacted in 1944 as a general updating of the scattered and confusing statutes on which the Public Health Service had developed through the years. It would be difficult to devise a broader author-

ization and directive than that found in section 301 of the act which declares:

> The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams.[20]

In carrying out this mandate the Surgeon General is authorized to utilize various techniques, including the collection of information as to research and its practical application, such information to be made available "through publication and other appropriate means." This openness of approach is further emphasized by the authority explicitly conferred to make available the research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in research, and to make grants-in-aid to institutions and individuals for research projects recommended by the various advisory councils of the Service. Broad as are the general directives of section 301, it is only one of many references to information and research, and to making available the results of research, which are scattered through the Public Health Service Act as it has developed by amendment through the years.[21]

The Federal Water Pollution Control Act,[22] which is also administered by the Surgeon General under the general supervision of the Secretary, serves interests which include but are more diversified than those of health. It confers research authority modeled upon the provisions of the Public Health Service Act, including specific authority to procure research through contract.

The vocational rehabilitation program, administered in the Department and given new breadth and impetus by legislation passed in 1954, now has authority and funds to make grants for research and to establish research fellowships.[23] Following the report of a citizens' advisory committee, for which Congress appropriated funds in 1954, the laboratories of the Food and Drug Administration have responded and will respond further to the vigorous expansion of this agency on which the nation depends for the safety and purity of its foods and medicines.

The Office of Education whose traditional function has been the collection and dissemination of information about schools and educational methods has recently, through the National Defense Education Act, been given specific responsibilities for research in the more effective use of visual aids and is thus brought into a field from which patentable inventions may be anticipated, again with emphasis upon public information concerning the results.[24] At St. Elizabeths Hos-

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[20] 42 U.S.C. 241.

[21] A partial list of such provisions includes: 42 U.S.C. 242 (narcotic drugs); 242a, 242b (mental health); 242c (national health studies); 244a and 245 (vital statistics); 247 (publication of public health information); 275 (National Library of Medicine); 282 (cancer institute); 287 (heart); 288 (dental research); 289a (authorizing additional institutes, enacted in 1950 with a strong congressional declaration of purpose); 291n (hospital development and utilization).

[22] 33 U.S.C. 466c. Water Pollution Control Act Amendments of 1956; 70 Stat. 498. This is in effect a new statute replacing the Water Pollution Control Act of 1948.

[23] 29 U.S.C. 34.

[24] 20 U.S.C. 541–542.

pital, the Clinical Neuropharmacology Research Center, operated by the National Institute of Mental Health, has recently been formed to study the relation of drugs to the problems of mental disorder.

The Committees on Appropriations, both House and Senate, in their reports on the Department appropriations for the fiscal year ending June 30, 1960, evinced an enthusiasm for the research programs of the Department, particularly in the health field, which overrides the limitations of executive budgetmaking with considerable impatience.[25] The appropriation for the National Institutes of Health alone amounts to $400 million as against $293,383,000 for the last fiscal year, and approximately $44 million in 1953. Perhaps most indicative of the temper of the Congress is the fact that the increase of approximately one-third in the appropriation for 1960 was made in spite of the fact that no increase had been provided for in the executive budget.

Thus, through the swift developments of the postwar years, the characteristics of the Department, through its various constituent units, in the aspects most pertinent to questions of patent policy have shaped themselves in terms which may be summarized as follows:

1. The Department in its entirety is directed to the conservation and improvement of the human resources of the Nation.
2. The research activities of the Department, already the most extensive of any agency of the Government (outside of the Department of Defense, the Atomic Energy Commission and the new National Aeronautics and Space Administration), are rapidly broadening in base and increasing in the amount of support through appropriated funds.[26]
3. The bulk of the Department's research activity is in the field of medical research, a field in which its programs account for more than 80 percent of total Federal expenditures.[27]
4. In its research programs the Department by statute has a cooperative relationship with public and nonprofit agencies and with individual members of the scientific community, administering in this connection a large number of grant programs.
5. The Department by statute is charged with the function of disseminating information and making public the results of research.

What is, and what should be, the relation of a governmental agency, thus wholly oriented to a nonexclusive, nonproprietary, and informational approach, to a patent system which is founded on the concept of a benefit to the "inventor" to be derived from the conversion (after a period of zealously safeguarded confidentiality) of an invention into a form of property which is principally characterized by the power to exclude others from its use for a period of years?

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[25] See lengthy discussion of the research activities of the Service and criticism of the Executive budget for 1960, in the report of the House Committee on Appropriations on H.R. 6969, the appropriation bill for the Department of Health, Education, and Welfare, pp. 8–19, and in the report of the Senate Committee on Appropriations on the same, pp. 19–40.

[26] See special analysis on "Research and Development" included in the budget for fiscal year 1960, p. 990. See also, "Federal Funds for Science VIII—The Federal Research and Development Budget," National Science Foundation, fiscal years 1958, 1959, and 1960.

[27] The Department share of total Federal expenditures for medical research rose from 52 percent in 1953 to more than 80 percent in 1959. Ibid., table 13. See also "The Advancement of Medical Research and Education Through the Department of Health, Education, and Welfare," report of the Bayne-Jones Committee of Consultants on Medical Research and Education, p. 27.

This monograph will attempt to answer that question in the light of the history of the patent policy of the Department of Health, Education, and Welfare. It will do so on the assumption that the head of the Department has authority, in the absence of express statute or controlling Executive order, to specify prospectively that relationship with respect to inventions made by employees of the Department, by grantees or employees of grantees, or by contractors and subcontractors and their employees, made within the scope of the Government employment, grant or contract, or with a substantial Government contribution.

It is appreciated that the location, in Government, of authority to specify the terms of employment, of a grant, or of a procurement or other contract may present a legal problem of considerable difficulty. It is not a part of the purpose of this paper to examine extensively the locale of such authority. The existence in Government, at some point, of legal authority to fix the terms of such contractual arrangements is, however, hardly open to question. The *Dubilier* case in the Supreme Court represents the high-water mark in the confirmation of private rights in an invention made by Government employees with the use of Government time, equipment and facilities but for purposes not specifically within the scope of their assignments.[28] The majority of the Court likened the position of the Government to that of any private employer, and found that the circumstance of the case, including previous practice in the Bureau of Standards where the inventors were employed, negatived the implication of any agreement to assign, express or implied. Justice Stone's dissenting opinion, in which he was joined by Mr. Justice Cardozo and Chief Justice Hughes, considered that the employment in this case did embrace the exercise of inventive faculties and viewed the result of the majority opinion as repugnant to principles of equity. It additionally noted that—

> the case would be more dramatic if the invention produced at public expense were important to the preservation of human life or the public health.

In any event the decision by no means indicates a lack of authority in the Government to establish a policy which would control the disposition of inventions made by its employees. The Court noted the absence of declared congressional policy but was not required to pass upon the sufficiency of administrative controls because none had been established in the case before it.

The assumption, stated before, of authority in the head of the Department of Health, Education, and Welfare is presented without examination at this point largely in the interest of simplicity. It is, however, in accord with the conclusion reached in the Attorney General's report and recommendations to the President in 1947 as to the general authority of department heads.[29] In keeping with this view has been the adoption of regulations covering inventions and patents by the Secretary [30] who, by virtue of the reorganization plan creating

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[28] *United States* v. *Dubilier*, 289 U.S. 178 (1933).

[29] U.S. Department of Justice, "Investigation of Government Patent Practices and Policies," report and recommendations of the Attorney General to the President (hereinafter cited as the "Attorney General's report"), vol. 1, final report, pp. 19–20 (1947).

[30] Originally in form of Agency orders 110 and 110–1 issued by the Federal Security Administrator.

the Department, exercises the power of general supervision and control over the various constituent agencies. With respect to the determination of rights in employee inventions, and with respect to foreign rights generally, these regulations conform to the terms of Executive Orders 10096 and 9865 which deal, respectively, with rights in employee inventions and with foreign rights in inventions arising from Government-financed research. Executive Order 10096, the drafting of which followed the Attorney General's report and recommendations, was issued in January 1950 and was generally thought to establish, as its terms relate, "a basic policy for all Government agencies with respect to inventions hereafter made by any Government employee," thus filling the void which had been found to exist in the *Dubilier* case. No question of controlling authority was therefore thought to exist at the time of the original adoption of policy by the Federal Security Agency. (See, for later developments under Executive orders, p. 12 and footnote 116.)

It is worth noting, moreover, that a conflict of authority might arise and indeed in the past has arisen, between an agency of the Government armed with managerial authority of a broadside nature relating to Government property and the treatment of patents based on research conducted under a statutory mandate to serve a broad public need. See infra, pages 49 and 62. That the purposes of the research program should control the disposition of patent rights of this nature seems clear.

A final assumption in this study is the continuation of the patent system in its present form except for modification which may be indicated to adapt it to the needs of the Government itself as the potential owner of rights arising from inventions which it has itself financed or supported. Quite possibly the experience of this one Department may contribute significantly to the present reexamination of the relation of the patent system to research in general. Certainly the conclusions reached in Professor Melman's study [31] as to the growing disparity between the patent system and the promotion of new knowledge under modern conditions are provocative reading for those interested in Government, as well as in industrial and university, research.

The present study, however, is confined to the area of experience and thinking of the Department of Health, Education, and Welfare within the framework of the existing patent system and with regard to the objectives and facilities of the Department.

2. DEVELOPMENT OF DEPARTMENT POLICY

(*a*) *Prior to policy formulation by Federal Security Agency*

What may be called the significant prenatal history of the Federal Security Agency in patent matters was largely confined to the Food and Drug Administration and the Public Health Service. The two agencies differed in nature. The first, although a part of the Department of Agriculture which itself had broad research functions, was primarily occupied with enforcement activities under the original Food and Drug Act.[32] In the handling of inventions developed by its

[31] Melman, Seymour, "The Impact of the Patent System on Research" (study No. 11, U.S. Senate Subcommittee on Patents, Trademarks, and Copyrights).
[32] Act of June 30, 1906; 34 Stat. 768.

employees, it was subject to the regulation of that Department which had evolved a policy, expressed in departmental regulations and memorandums, by which domestic rights in inventions developed by employees in connection with their work were generally subject to assignment to the United States, while foreign rights were left to the inventor.[33]

From 1928 until the Food and Drug Administration was transferred to the Federal Security Agency in 1940, four patents were issued on inventions resulting from its function.[34] After the transfer, the practice of assignment of the domestic rights was followed, as before, and the assistance of the Department of Justice was sought and obtained in prosecuting the patent application as a "public interest" invention under the act of March 3, 1883, as amended, the so-called nonfee statute.

In the case of the Public Health Service there had been a substantial history of research prior to the transfer to the Agency. A memorandum from Surgeon General Cummings in 1925 records the general policy in these terms:

> In conformity with the ethical practice of the medical profession, new processes in the field of public health developed by officers and employees of this Service have without exception in the past been thrown open to the public for the good of mankind without the restrictions which usually attend the procurement of patents in the commercial field generally.[35]

The case of *Houghton* v. *United States* [36] represented a strong and successful assertion of the right of the United States to the ownership of an invention developed by employees of the Service pursuant to a research assignment. Houghton was a chemist in the Office of Industrial Hygiene and Sanitation, and the invention was a fumigant gas, useful in the disinfection of vessels and less dangerous than gases previously used for the purpose. Houghton's three associates had dedicated to the public their interest in the invention; Houghton, however, filed a patent application and was unwilling to offer the Government more than a license for its own use. The Surgeon General, acting under advice of the Solicitor of the Treasury Department, challenged the grant of the patent to Houghton. In the ensuing litigation the circuit court of appeals held that the United States was the equitable owner and entitled to assignment of the patent. The opinion is notable for its comment upon the scope of the public interest in Government research for a health purpose:

> The Public Health Service represents the people of the United States. Its interest is their interest. Its inventions, investigations, and discoveries are made for their benefit. And although neither it nor they have any interest in monopolizing inventions which may be made in the course of its studies and experiments, both have an interest in seeing that the inventions are not monopolized by anyone. It is unthinkable that, when a valuable instrument in the war against disease, is developed by a public agency through the use of public funds, the public servants employed in its production should be allowed to monopolize it for private gain and levy a tribute upon the public which has paid

[33] Department of Agriculture Regulation No. 1561 (1936) and Memorandum 731 (1937).
[34] See, on this early period, the "Attorney General's report," monograph on the Federal Security Agency, p. 152. The four patents mentioned apparently were not transferred to the Federal Security Agency files.
[35] Memorandum of Feb. 9, 1925, to Secretary of the Treasury Mellon (in the Department of Justice file in the *Houghton* case).
[36] 23 F. 2d 386 (4th Cir., 1928).

for its production, upon merely granting a nonexclusive license for its use to the governmental department in which they are employed.[37]

The *Houghton* case is both evidence of initiative on the part of the Service to protect the public interest in the product of its research efforts and of judicial recognition of the broad nature of the public interest in the product of Government research.

By regulation, apparently adopted after the *Houghton* case, the Public Health Service provided that:

> Any officer or employee of the Service who invents or discovers any new and useful art, machine, manufacture, or composition of matter connected with the work of the Service through the expenditure of Government time and funds, or with the aid of Government facilities, will secure the approval of the Surgeon General before applying for letters patent thereon and said letters patent will, if so determined by the Surgeon General, then be secured in the name of the inventor without expense to him and in such manner as to allow the U.S. Government, or any citizen of the United States, to use the subject of said patent without the payment of royalties.[38]

The language as to the scope of the license was founded on the nonfee statute which authorized the prosecution without payment of Patent Office fees of patent applications on inventions of Government employees, regardless of the relation of the invention to their official duties, provided in each case that the head of the agency in which the inventor was employed certified that the invention was one "liable to be used in the public interest." [39] After the decision in the *Dubilier* case, in cases where the invention was not made as a part of a specific assignment, the regulation was construed not to require a license for other than Government purposes.

Before the transfer of the Service to the Federal Security Agency a number of inventions made by employees of the Service did become the subject of patent applications and assignment of rights to the Government as represented by the Secretary of the Treasury.

One group of four inventions was of particular interest to the Bureau of Narcotics (then as now a part of the Treasury Department), because they involved narcotic derivatives and were significant, therefore, not only for medical use but in connection with the control of the drug traffic. Of these, two at least were held unavailable for licensing because of the dangers attending their use. The patent entitled "Nuclear Substituted Derivatives of the Morphine-Series and Methods for Their Preparation," known as Metopon, was, however, licensed to a number of pharmaceutical houses, under limiting conditions in accordance with advice from the Bureau of Narcotics. Following the transfer of the Public Health Service, responsibility for administration of these patents was transferred to the Federal Security Agency.[40] Nonexclusive royalty-free licenses for Metopon continued to be issued to pharmaceutical houses by the Agency. It is noteworthy that the Committee on Drug Addiction and Narcotics, of the National Research Council, later formally agreed that there

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[37] Ibid., at 328.
[38] Regulations of the Public Health Service (1935), par. 305.
[39] Act of Mar. 3, 1883, as amended; superseded by 35 U.S.C. 266.
[40] The patents transferred from the Treasury Department are indicated in the list in appendix E, "List of Government-owned patents on inventions arising from activities of the Department of Health, Education, and Welfare (or predecessor agencies)." Letters relating to the transfer of administration are in Department files. See, for example, letter of Robert Cassels, then Federal Security Agency Patent Officer, to Archie Palmer, Chairman, Government Patents Board, Apr. 3, 1951.

was no present need for continuing restrictions upon manufacture and sale of Metopon other than those imposed by the Federal narcotics laws and regulations. In this recommendation the Secretary of the Treasury and the Federal Security Administrator concurred, and the advice and assistance of the Department of Justice was solicited to effect a dedication of the patent to the public. This was the first, but as will be seen, not the last use of a patent control to effect the equivalent of an exercise of Government regulatory power.

At least six other patents on inventions made by Public Health Service employees while the Service was a part of the Treasury Department, and which had been assigned to the United States as represented by the Secretary of the Treasury, were identified, and responsibility for their administration transferred to the Federal Security Administrator, as an incident to the transfer of the Public Health Service. In the case of at least two of these inventions the records indicate the conclusion of license agreements by which the Government became entitled to the use of certain inventions for which patent applications had been made by private licensees. These appear to be the only instances on record of a cross-licensing agreement on the part of the Agency or its successor, the Department of Health, Education, and Welfare.

In the field of grants, where the authority to impose conditions designed to effect the research purpose was undisputed, the Service acted quickly to lay a foundation for control of inventions arising from the aided research. As of 1940 its awards of research grants and fellowships were made subject to the following conditions:

> If any patentable discoveries or inventions are made in the course of work aided by any grant received as a result of this application, the applicant will, in consideration of such grants, refer to the Surgeon General of the Public Health Service, for determination, the question of whether such patentable discoveries or inventions shall be patented and the manner of obtaining and disposing of the proposed patent in order to protect the public interest.

This clause put the means of control into the hands of the Surgeon General. Unfortunately it lacked effective implementation. No policy was developed to indicate either the conditions under which patenting would be determined or, if a patent were obtained, what would be considered useful "to protect the public interest." The Service was, moreover, ill-prepared to cope with the problems of patent administration. The absence of criteria or precedents to govern the Surgeon General's decision in actual cases troubled both the grantee institutions and the administrators of the grant programs.

The fact that the public grant was frequently only one source of contribution to the research project was also a factor which led to an examination of patent policy by the National Advisory Health Council. This is the first and most basic of the statutory councils created to advise the Surgeon General on matters relating to medical research, having particularly the function of reviewing and recommending to the Surgeon General research projects upon which grants may be made. In 1947 this Council, following a presentation by the head of the research grants division, informally recommended that there be indicated, in the grant application form, a stipulation that the grantee would not be restricted by the grant in obtaining and administering patents on inventions arising therefrom except for the reservation of a license for Government purposes.

It was recognized that a proposal which would leave to the grantee's unrestricted discretion the disposition of the inventive product of its research grant raised policy questions of concern to the Agency as a whole and called for consideration by the Federal Security Administrator in his role of general supervision and direction. Legally it presented the question of whether such a disposition of inventions, without limiting conditions designed to protect the public interest, could be squared with the explicit directive of section 301 of the Public Health Service Act to make information as to research and its practical application available "through publication or other appropriate means."

The resolution of the policy problem with respect to research grants of the Public Health Service reflects from this point on the broader discussions which took place at the Agency level.

(*b*) *Formulation of policy by Federal Security Agency*

Thus, before a decade had elapsed the Federal Security Agency was aware of the conflict presented by its public-service-oriented research programs and the pressures of the patent system to convert inventions into fixed proprietary rights. Two factors particularly served to precipitate discussion. The first was the beginning of the great growth of research in the health field, conducted or sponsored by the Public Health Service, principally through its National Institutes of Health as shown by the tables and charts in appendix J, p. 91.

The other factor was the inquiry concerning Agency policy received from the Department of Justice in the course of the study it was conducting preparatory to the Attorney General's report and recommendations to the President. The Federal Security Administrator at that time indicated that the Agency had not as yet developed an agencywide policy, but expressed wholehearted agreement with its basic recommendation which favored the Government's right to require assignment of inventions made during working hours, with a substantial contribution by the Government, or bearing a direct relation to the employee's official duties.[41] He anticipated that the report of the Attorney General would be helpful to the Agency in its own policy formulation.

The Administrator, in his reply to the Attorney General's inquiry, passed on the individual comments of the constituent organizations (the Public Health Service and the Food and Drug Administration) which had had considerable experience with patents and also the philosophy with respect to their research efforts voiced by various related units. For example, the Superintendent of the American Printing House for the Blind, an organization having a statutory relationship to the Agency although not actually a part of the Government, reported that during the 87 years of its existence it had made valuable contributions to the art of printing for the blind; it had taken out no patents and regarded itself as a unit which works together to promote the interest of the blind without any thought of personal gain through the contribution of original ideas.[42]

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[41] Letter of Federal Security Administrator to John Sonnett, Department of Justice, Sept. 17, 1945.

[42] Letter of A. C. Ellis, superintendent, to Harry Rosenfield, assistant to the Administrator, Sept. 6, 1945.

In 1949 the Federal Security Administrator appointed a committee "to study the patent problems of the Agency and to formulate recommendations for an agencywide patent policy." The committee brought together in a working group, representatives from the Social Security Administration, the Office of Education, the Public Health Service, the Office of the Administrator, the Food and Drug Administration, and the Office of the General Counsel of the Agency. It had for its chairman, Mary E. Switzer, now Director of the Office of Vocational Rehabilitation, but at that time serving as liaison officer for the Administrator with the Public Health Service, after years of experience with its problems in the Treasury Department and invaluable experience as well with the war-time contracts of the OSRD (Office of Scientific Research and Development).

The report of the committee was made on June 7, 1950, and was approved as the basis for the Agency orders (110 and 110–1) which followed.[43] The committee report is not only the basis for these implementing orders, but it was, and remains, the most complete exploration of Agency policy and the reasons therefor. Because of its well-rounded presentation of the factors which led, with gathering assurance, to policy conclusions to which the subsequently created Department has adhered with slight changes, the report of the committee appears in full as an annex to this study (appendix A, p. 66).

The most salient conclusions reached at that time may be stated thus:

1. All inventions made by Agency employees which are directly related to their official functions or to which the Federal Government has made a substantial contribution should be owned and controlled by the Government for the public benefit.

2. The nature of the Agency, being devoted to programs related to health and welfare, particularly compels this conclusion. The cooperative nature of the efforts in which its research staffs are engaged also warrants the requirement that the research product of the staff so engaged should belong to the Government.

2. A patent in the name of the United States, as owner, is merely a means of assuring the availability of the invention to the public, subject only to such controls as may be needed to protect the public health and safety.

4. In the case of grants for research, the basic objective is the same: i.e., the development of knowledge and of techniques for use as broadly as possible for the public health and welfare, the dissemination of information being a specific duty to this end.

5. A clause reserving the right of determination to the grantor agency, as previously used by the Public Health Service, should be retained in grant applications. Guidelines laid down for the exercise of the discretion thereby reserved may admit of assignment to other than the United States provided the grantee gives adequate assurance that the invention would be so administered that it would be readily available to the public, to science, to Government, and to industry.

[43] Agency order 110, signed July 10, 1950. Agency order 110–1, dealing with grants, supplanted pt. IV of Agency order 110 and was signed Sept. 15, 1952.

6. Inventions resulting from cooperative research as to which a substantial contribution has been made by others, may be left to the grantee for assignment to a qualified organization for a limited period, for the purpose of developing and exploiting the invention, with reasonable safeguards against unreasonable royalties or repressive practices. Such action, however, is to be taken only with the express approval of the Administrator in exceptional cases where it is found that by such an assignment the fruits of the invention may be "made available to the public more quickly, more economically, in larger quantity or better quality."

The last point reflects the readiness of the Agency to recognize, and put to the test of experience, the oft-repeated assertion that only through patenting and exclusive control of their marketing, for at least a period of time, can the values of some inventions be realized for the public benefit. Inventions arising from research conducted under grants afford in this respect a latitude not open to the Government since numerous grantee institutions, having authority to acquire patents, have authority (believed not to be open to the Government in the absence of legislation for that purpose) to issue exclusive licenses.[44]

Members of the committee, while appreciating the possibility that development of an invention might sometimes be delayed unless exclusive control of it could be permitted for a temporary period, recognized also—

1. The difficulty of informed forecast and judgment in matters involved commercial development;

2. The dangers inherent in any action by a Government agency giving preference to any private interest in inventions financed even in part by the Government;

3. The possible strengthening of a monopolistic interest in a particular field by organizations already controlling patents in that field.

These, then, were the concepts (and the caveats) underlying original Agency order 110, which were to be tested by actual experience, both within the Agency and particularly in the Public Health Service where the bulk of its research activity was conducted. In the order, the criteria for the determination of employee rights followed the language of Executive Order 10096, which had been issued by President Truman on January 23, 1950, and which (although containing puzzling ambiguities not found in earlier drafts upon which the Agency had been asked to comment) was not considered to present any point of conflict with the thinking of the committee. The further work of the committee in developing the draft Agency order as it related to employee inventions dealt with machinery and procedures which would conform to the Executive Order.

There was set up at this time an Agency Patents Board, consisting of five members, to advise and consult with the Administrator and the constituent agencies on patent matters, and to hear and determine appeals from determinations made on behalf of the Agency. The position of Agency Patents Officer was also created, such officer to act as secretary and executive officer of the Board; to act as repre-

[44] For an exposition, frequently cited, of the Government's authority with respect to patent administration generally, and particularly the constitutional objections to exclusive licensing, as an attempt to dispose of a property right of the Government in the absence of statutory provision therefor, see 34 Atty. Gen. 320 (1924).

sentative or alternative representative on the Government Patents Board; to receive all determinations (made in the first instance by the head of the constituent unit of the Agency in which the inventor was employed), and refer, if necessary, to the Department Patents Board for determination; to be responsible for Federal records; to advise with constituent units, and to issue, with the Board's approval, needed procedures, bulletins and instructions.

As to patenting the Agency order stated that the Agency will file a domestic patent application on inventions in which the Agency has an interest, provided circumstances indicate that this is necessary in the public interest and if it is practicable to do so. However, it declared that it is usually desirable for the results of Agency research to be made widely, promptly, and freely available to other research workers and to the public, and that, in many cases, this availability can be preserved by dedicating to the public through publication. The fact that a patent application has been filed, it was stated, will not ordinarily require any departure from normal practice regarding timely publication of the research. Licenses under patents for which the Agency is responsible will be royalty-free, revocable and nonexclusive. Also, except in unusual cases when determined to be contrary to the public interest, licenses will be issued to all applicants and contain no limitations or standards relating to the quality of the product to be manufactured, sold, or distributed.

The last provision is especially significant coming as it does from the Agency which included the principal governmental units charged with the safety of drugs and related devices for human use. It meant that the Agency would not ordinarily look to the chance ownership of a property right, exercised through a patent, to achieve the regulation of their manufacture and content.

The establishment of the Agency Patents Board (later to become the Department Patents Board) and the naming of a Patents Officer meant that, for the first time, there was provided a forum in the Agency for the consideration of patent matters from a broad policy standpoint, and a channel for the handling of inventions at the Agency level. Basically, the same machinery has continued. It has functioned with considerable vigor, considering the perplexity and time-consuming nature of the problems involved and considering the fact that they are entirely peripheral to the basic responsibilities of the officials who have served in the capacities required by the Agency's order. The factor of continuity has been of the highest importance because it has meant that the problems arising in the administration of the policy have had the benefit of ripening experience and the assurance that comes from group discussion of unfolding problems. It has also meant that succeeding Administrators and Secretaries (of the later Department of Health, Education, and Welfare) have had an advisory body with which to consult in the formulation of policy questions. In the absence of such a body policy problems would have had to be dealt with either on the basis of a disclaimer of any prepared policy (as in the reply to the inquiry from the National Patent Planning Commission in 1943)[45] or on the basis of views and

[45] Letter of Aug. 25, 1943, from Watson Miller, Acting Administrator, Federal Security Agency, to A. A. Potter, Executive Director, National Planning Commission.

experience not representative of the total Agency or Department experience.

Agency orders 110 and 110–1 were revised in 1952, prior to the transfer of the Federal Security Agency to the newly created Department of Health, Education, and Welfare in 1953. In part, these revisions were necessitated by the sharp curtailment of funds available at the Agency level for purposes of general supervision and control. Sharp reductions in force affected the Office of the General Counsel where a chief attorney's incidental duties as Patents Officer has come to absorb his full time. By the revision the review functions of the Board were changed to a purely optional role (considered sufficient in view of the mandatory right of appeal by employees to the Government Patents Board). Greater responsibility as to final determinations was placed on the heads of the operating units of the Agency. It was provided that, in the absence of appeal, the determination of the head of an operating unit should become the final decision of the Administrator unless, upon review, the Agency Patents Officer questioned its consistency with applicable law or Agency policy, in which case these should be referred to the Board.

More significant from the standpoint of the extra-Agency relations were the changes relating to research grants (at that time in practice limited to the Public Health Service). Whereas the right of determination has been reserved to the Surgeon General (as the grantor) in all cases, Agency order 110–1 of September 15, 1952, provided for leaving the disposition of rights in some cases to the grantee. It also, however, contained a "march-in" clause reserving power to the Surgeon General to grant nonexclusive royalty-free licenses upon his determination that the patent had been used to exact unreasonable royalties or support other repressive practices adverse to the public interest. Objections from grantee institutions led to early change in this provision. The revision substituted for the march-in power a provision for acceptance in advance of the institution's policy, where this was established (or could be modified by agreement) in a way to give assurance that abuses against which the march-in clause had been directed would not occur. Where such an agreement existed the disposition of inventions was to be left to the grantee institution according to the terms of the agreement. In the absence of agreements, however, the Surgeon General was to make individual determinations as before.

The policy thus formulated remains substantially unchanged, with 19 institutions now operating under agreements for the handling by the institution of all inventions arising from Public Health Service grants. See list and sample agreement—appendixes G and H, pages 88 and 89.

In the formulation of its grant policies the Agency appreciated very well the significance of its action in throwing its weight behind an approach which would generally result, and has resulted, in the prompt and full dedication to the public of the results of the aided research. It acted in full cognizance also of variance from the laissez-faire policy of the National Science Foundation which, under its support grants, leaves to its grantees full control over the disposition of inventions arising therefrom, subject only to a license to the Government. It considered, but rejected also, the policies of those

universities which adhere to the view that the results of research conducted at the institution should be patented and administered primarily as a source of income for the support of further research activities or for general university purposes.

The most serious obstacle, however, to the adoption of what seemed to the Agency an appropriate policy for research in the general public interest, was the often encountered contention that its research grants, in its patent clauses, should conform to the contract clauses of other agencies of the Government, particularly those prescribed by the Armed Services Procurement Regulations. Whatever the propriety of so restricted a claim in the case of the military departments, it was deemed inadmissible for research conducted for the information and benefit of the general public.

In the negotiations which have led to the acceptance (sometimes with important modifications to bring them in line with the limitations of the Department regulations) of the policies of a number of universities and other nonprofit institutions (19 agreements to date) to govern the disposition of inventions arising from its grants, a process of increased understanding and support for the basic objectives of the research activities of the Service was set in motion. This included understanding of the reasons why those objectives, involving the dissemination of information and dedication to the public of the results of research, differed from those, for example, of the Defense Department which engages in research primarily to supply the needs of the Government itself.

With Federal agencies having general managerial functions with respect to property, reiteration was required of the reasons why the results of inventions, even when patented, could not be narrowly regarded as an ordinary property right. For example, in 1945 the Surplus Property Administrator inquired as to patents or inventions in the possession of the Agency which were "not needed" to carry out its responsibilities and which, therefore, it would declare surplus under the Surplus Property Act of 1944, as amended.[46] The Agency in reply advised that it did not anticipate declaring any such interest to be surplus. In considering the application of section 19 of the Surplus Property Act to the Agency, the Agency was mindful of the fact that its own responsibilities lay in the field of health and welfare and that in carrying out its functions, it worked in cooperation with State and local governments and also with large numbers of nonprofit institutions. It cited a substance of value in the field of cancer research as a recent invention developed by an employee in carrying out the health research function. The disposition of inventions of this nature to private interests giving them exclusive rights would hardly be compatible either with the responsibilities of the Agency or with the intent of Government employees voluntarily making such assignments for the purpose of serving the public interest. No record has been found of further pursuit of this inquiry from the Surplus Property Administration.

[46] Letter from W. Stuart Symington, Administrator, Surplus Property Administration, and reply of Dec. 10, 1945, from Watson Miller, Administrator, Federal Security Agency.

(c) *Consideration of policy by Department of Health, Education, and Welfare*

The Department of Health, Education, and Welfare dates from April 11, 1953. The general Agency policy with respect to inventions has been continued without basic change under successive administrations in the new Department.

The Department of Justice in that same year, stirred by the backlog of patent litigation in the Court of Claims, discontinued its assistance in the prosecution of patent applications, a service it had been rendering to Government agencies unequipped with patent attorney staffs of their own.[47] The Department of Health, Education, and Welfare could not, if it would, with the limited appropriations available for its Office of General Counsel, have made up for this withdrawal of service from the Justice Department by building up a staff of attorneys qualified as specialists in the patent field. Accordingly when the Department of Justice returned to the Department the files relating to its pending patent prosecutions, the justification for continuing the patent applications at Government expense was reexamined. This proved a salutary experience. Some applications were found lacking in substantial merit; for others, publication was deemed adequate to protect the public interest.

Increasing experience with the administration of patents also led at this time to increasing skepticism as to the value of the patent technique for the Government. At the time the Department was established in 1953 only two patents for the administration of which it was responsible had been made subject to conditional license; on all others licenses were issued on request and were only of paper significance. Under these circumstances, and despite traditional practices in other agencies, the Department Patents Board was not persuaded of the utility of the patent and license process and requested the further development of techniques which would both advertise the availability of new inventions to the public and protect against private appropriation by others under the patent system.

Such a policy, it was recognized, might be disappointing to some employees who had come to regard Government-financed patents as a form of honorary recognition or award. It might keep the new Department low on the list of Government-owned patents and might, though it should not, give it a weaker voice on the Government Patents Board. By this time, however, the Chairman of that Board, then Mr. Archie Palmer, had issued a list of 3,658 Government-owned patents, and the multiplication of these for purely defensive or prestige purposes was already causing concern to the overburdened Patent Office. Mr. Palmer and Mr. Green of the Office of Technical Services of the Department of Commerce, contributed helpfully to the exploration at that time of channels of technical disclosure and publication to supplement various scientific and technical journals.

For both employee inventions and inventions arising from work supported by grants, dedication by publication, without recourse to the patent process, has become standard policy of the Department. Under the orders of the Chairman of the Government Patents Board a determination that the Government is entitled to the entire right,

[47] Letter of Sept. 4, 1953, from Assistant Attorney General Burger to the Secretary of Health, Education, and Welfare.

title, and interest in an employee invention is not, except in case of appeal by the employee, subject to review by the Chairman; determination that the interest of the Government would be adequately protected by publication has, however, been subject to review. Although the absence of objection in the specific case may reflect no more than a "wait-and-see" approach, the Chairman, up to the writing of this study, had in no case objected to the Department's determination against patenting and in favor of publication. The Department's policy, at any rate, represents a middle ground between undesirable alternatives, i.e., the amassing of Government-owned patents devoid of normal patent significance, or a general abandonment to private and potentially monopolistic interests of the fruits of publicly financed research.

(*d*) *Consideration of policy by Department of Health, Education, and Welfare—The impact of contract research, industrial and other*

The terms upon which industrial cooperation can be enlisted in a major research attack on disease constitute a new challenge to the Department's concept of the public interest in the patent field. Spurred by the hope that some combinations of chemicals might hold the key to the relief or cure of cancer, Congress for the fiscal year 1956 included in its appropriation for the cancer program authorization for cancer chemotherapy research contracts and clothed the Surgeon General with power to enter into research contracts free of some of the controls normally attendant on Government contract negotiations. Amounts available for this purpose increased from $900,000 for the fiscal year 1956 to $21,142,000 for fiscal year 1960.

The program envisaged the coaxing from the shelves of the large chemical and drug companies, for testing purposes, of a vast number of compounds and chemicals whose utility was as yet unestablished, and the formula for whose manufacture was as yet undisclosed. The first test of the Department's patent policy arose in connection with the so-called screening contracts for these compounds. These supply contracts called for the furnishing of compounds for testing, according to a prescribed formula, for anticancer properties, such testing to be carried out on animals only (usually mice). The problem involved was not so much one of immediate invention, the possibility of which was largely excluded by the routine and rigidly controlled nature of the tests themselves, as laid down by the Service, as it was of reconciling the supplier's interest in preserving the confidential character of the tested compounds with the primary interest of the Service in the disclosure of the results of research for the benefit of the public.

This problem was resolved by the adoption of policy controls [48] (pursuant to which tightly drawn contract patterns were evolved) which apply exclusively to the situation in which a supplier furnishes, for controlled screening and testing purposes only, compounds or products not otherwise available to the Service and in which the supplier has a proprietary interest. The contracts in these cases may provide that all rights in the compounds or products shall remain in the supplier. The Surgeon General may additionally provide for confi-

[48] Department Manual, 6–10–20. "Patent Policy Applicable to Chemotherapy Industrial Research Contracts: C. Contracting With Suppliers for Screening and Testing Only." Appendix B, infra, p. 78.

dentiality of the results for a limited period after the completion of the screening process and the report of the results by the Service to the supplier. This period, as to results deemed significant for the research purpose, may not, however, exceed 1 year. When the screening and testing is carried out by an outside laboratory the rights of the supplier are safeguarded in the contract of the Service with the testing laboratory.

Difficulty over the patent clauses developed in the negotiations of industrial contracts for research, including that in which new developments in the cancer field were considered the most likely to arise, namely, the production and process of extraction of cultured filtrates from antibiotic beers. The cost of extraction of these filtrates is high and the investment necessary for facilities and equipment is substantial. Enlistment of the efforts of large chemical and pharmaceutical companies was considered to be essential to the dynamic mass attack on this approach to the cancer problem envisaged by the Congress.[49]

Up to this time the authority of the Service, with respect to the conduct of research programs by others, was limited almost entirely to grant programs, and to dealings with nonprofit organizations. Department regulations with respect to contract research were not spelled out in the regulations but were deemed to call for the application of criteria consistent with those applied in the case of grants. Already, however, contract research authority was being extended to other programs of the Service and of other agencies of the Department. General legislation has now extended to all agencies having authority to make contracts for basic research with nonprofit organizations, authority to employ the grant technique as well.[50] The 1960 Appropriation Act for Health, Education, and Welfare extends contract authority to all research or training projects of the Service under the appropriation without limitation to contracts with nonprofit organizations.[51]

The problem confronting the Department, as first considered by the Department Patents Board, was precipitated by difficulties reported to the Board in the negotiation of the cancer chemotherapy contracts. It involved the extent, if at all, to which the basic policy criteria would need to be modified to meet the pressures existing in connection with the chemotherapy program. Inevitably, however, this raised the problem of the extent to which such modifications should be treated as an exception rather than as a new general rule.

The situation was anomalous in that the case for ownership of invention rights by the Government is most strong when it results from contracts, in the nature of procurement contracts, in contrast to inventions arising from research under grants to nonprofit organizations which are founded on the concept of benefit to the grantee in its research activities as well as support for a particular project. In the case of the industrial contract, however, where, as in the cancer chemotherapy program, the need for a particular type of research

[49] See special report to the House of Representatives, "Participation of the Pharmaceutical Industry in Research in Cancer Chemotherapy," submitted by Dr. Kenneth M. Endicott at the request of Mr. Fogarty, chairman of Subcommittee on HEW Appropriations for 1959, pp. 819–822.

[50] 42 U.S.C. 1891.

[51] Appropriation Act for the Department of Health, Education, and Welfare (73 Stat. 339) for fiscal year 1960, under Public Health Service, appropriation for "general research."

may be critical and the factor of competition not strong, the question of the bargaining position of the Government may become crucial.

Presentations to the Department Patents Board, and the ensuing discussions, involved what amounted to a resurvey of the Department's entire patent policy. Participation by operating program and administrative units within the Department in this discussion was broader and more informed by actual experience than had been the case when the policy was first formulated. The result of the general policy review at this time was a reaffirmation of the basic criteria with respect to all contracts with nonprofit institutions, including authority to leave the disposition of inventions to the institution if its policy had been accepted as meeting the requirements held necessary to assure protection of the public interest. The policy conclusion was the same with respect to other than nonprofit institutions. For these also the standard patent clause only is to be used, requiring a prompt report of any invention (first conceived or actually reduced to practice in the course of the performance of the contract) for determination, by the head of the constituent organization responsible for the contract, as to the manner of the disposing of all rights in inventions. This specifically includes, but is not limited to, the right to require the assignment of all rights to the United States or dedication to the public.[52] These provisions are spelled out in the regulations. (See also "Explanatory Statement With Respect to Contract Research and Research Grants," appendix D, p. 85.)

With respect to industrial research contracts of the cancer chemotherapy program the regulations provide for an exception to the general rule indicated above. These are subject only to such limitations and alternatives as the Secretary may approve for such program. The patent policy applicable to such research contracts is spelled out in the Department's Administration Manual, Patents and Inventions (6–10–20). These criteria, first approved in September 1957 and modified in August 1958, provide for the adoption either of the standard patent clause or, in the alternative, of a provision leaving all rights in resulting inventions to the contractor, subject only to a license to the Government and to a march-in power in the event of failure to meet the health need.

It would be absurd to dismiss, on the ground that they represent only an exception to general policy, any further account of the special provisions allowed for the contracts in this program. The program is directed to research to discover agents effective against the most dreaded of human diseases. Behind it, however, loom the potentialities of discovery in other fields, such as those of psychopharmacology, the opposition or reluctance of the drug companies to enlargement of Government research efforts in areas closely allied to production, and the jealousy with which the various companies protect their competitive position through tightly controlled patents. For this reason it may be illuminating to review the three stages in the application of policy to this particular program.

In enlisting the efforts of the large chemical and pharmaceutical companies in the chemotherapy research effort the Government was prepared to pay the full cost of the contracted research, including the construction of the necessary facilities. Contracts, under the normal

[52] 45 C.F.R. sec. 8.6, 8.2.

policy of the Department, would have provided that the inventive product of the research thus financed and paid for by the Government should be, as determined by the Surgeon General, either assigned to the United States or patented or otherwise disposed of under standards providing for the protection of the public interest in the case of all research financed by the Service. These standards, as has been seen, would admit of dedication of the invention to the public or, if the invention were patented, would assure its availability generally for royalty-free and nonexclusive patenting. It would admit also of assignment for a limited period to a competent organization for developmental purposes if it appeared that the invention could be more adequately and quickly developed for widest use and that there were satisfactory safeguards against unreasonable royalties and repressive practices. The contracting companies would thus be assured not only of full payment but, in addition to the leadtime and know-how of production techniques, would be assured that no competitor entering the field later would be given any preference.

As already indicated these assurances were reported to be insufficient to secure contracts. Special criteria for the cancer chemotherapy program were first approved by the Acting Secretary on September 9, 1957, accompanied by an explanatory statement as follows:

> The cancer chemotherapy program of the Public Health Service is an intensified effort, with special appropriations made available under a congressional directive, to explore exhaustively and rapidly the potentialities of chemical compounds in the control of cancer. Because of the peculiar exigencies of this program and in order that the resources of pharmaceutical and chemical firms may be brought to bear with a minimum of delay, certain exceptions to general Department policy will be permitted in the negotiation of industrial contracts for this program.[53]

Difficulties in contract negotiations continued. On the request of the Board for a formal report as to the factual situation, the Surgeon General informed the Board that it had been unable to conclude product-development contracts under the terms of the September 9, 1957, policy. In the course of the consideration of policy changes which followed, the Board had before it not only recommendations of the Service, but written comments of the legal committee of the American Drug Manufacturers Association transmitted by the president of the association and an opportunity was afforded certain industry leaders at their request to appear before the Board.[54]

Discussion centered upon the provision whereby the unlimited right allowed the contractor to control the product of research for health as well as other purposes would be offset by a power reserved to the Surgeon General to issue licenses under the patent to other companies, if he should deem it necessary to secure an adequate supply of the product for health purposes at a reasonable price and of high quality. This was the most sensitive point in the discussion. Indus-

[53] Department Manual, General Administration, 6-10-20 A. 1.

[54] See, for example, as a statement of the drug manufacturers' position, a paper entitled "The Washington Scene and the Drug Industry," by Karl Bambock, executive vice president, American Drug Manufacturers Association, reprinted in hearings before Senate Appropriations Committee, Subcommittee on HEW Appropriations, fiscal year 1959, p. 1679. On patents in relation to the competitive position of certain drug companies, see Federal Trade Commission report, "Economic Report on Antibiotics Manufacturers" (June 1958).

try leaders who appeared before the Board [55] urged that the power of publicity and public opinion would be sufficient to force general licensing if the facts of a situation justified it. They expressed fear, however, that the Surgeon General would be unable to resist the pressure for general licensing, even though sufficient justifying circumstances did not exist. It was suggested, as an alternative, that the contractor should be obligated to license only manufacturers to be selected by the contractor. The need of safeguards against capricious and arbitrary action by the Surgeon General was urged.

Final revision of the Department's criteria for industrial cancer chemotherapy contracts was announced August 5, 1958. Under it two alternatives are available. The contract may retain the "standard clause" reserving to the Surgeon General the right of determination as to inventions. Or the contract may leave the right to patent and exploit inventions to the contractor, subject only to various preliminary procedural steps to be taken in the event the public interest requires broader licensing and an ultimate march-in power in the Surgeon General either to dedicate to the public all rights in the invention, or to issue nonexclusive royalty-free licenses for practice of the invention for any health purpose on a nondiscriminatory basis to all qualified applicants. Prerequisite to the exercise of march-in power is a finding, following opportunity for a hearing, that the contractor has not met the public need and that public dedication or additional licensing is necessary in the public interest.

The basic change between the 1957 and the 1958 criteria may escape the casual eye but its significance should not escape the analyst. Under the 1957 version the right accorded the contractor (instead of the Government) to own and exploit the resulting inventions was in the nature of a provisional or conditional right terminable by the Surgeon General if in his judgment necessary to assure an adequate supply of the product for health purposes. Under the 1958 version the Government has contracted to give the contractor the exclusive right defeasible only after formal proceedings of a quasi-judicial character. The questions which present themselves are whether (1) the original surrender of the Government's interest is not too great, (2) the march-in power is not too blunt an instrument for residual control, and (3) the procedural provisions are not too clumsy a buffer between the two, the need for which might have been avoided had greater refinement in the basic contractual provisions been found possible.

It is too early to assess the practical operation of these provisions. It is certain, however, that insofar as the policy of the Department has been made subject to the exception which permits the contractor to retain the inventive product of Government-financed research, and to license its use on a pattern advantageous to its own interests, it represents a setback for the Department's basic policy. As succinctly announced in Chemical and Engineering News (issue of Aug. 18, 1958):

HEW policy now gives industry stronger patent position, right to exploit discoveries, right to choose licensees.

[55] Mr. John T. Connor, president of Merck & Co.; Dr. Ernest Volwiler, chairman of the board, Abbott Laboratories, and president, American Drug Manufacturers Association; Mr. Francis Brown, president of Schering Co. and of the American Pharmaceutical Association.

Such provisions may additionally advance the economically advantageous position of industries which are already marked by a high degree of concentration of power based upon patents.[56]

The most compelling forces in this action were: first, the nature of the program itself, with its deep emotional undertones of human fear and suffering; second, pressures on the Service brought to bear by the companies which in effect demanded, as the price of their participation and in addition to payment for their outlays and efforts, control of the commercial application of the inventive results; third, insistence by congressional committees responsible for appropriations that the Service speed up in this area through industrial research contracts;[57] and, fourth, perhaps, in a negative sense, the absence of statutory authority which might have placed the Department in a more flexible and effective position. Such legislation might take the form of a declaration of public purpose to make the results of such contract research available to the public, for widest use and at reasonable cost, but authorize exclusive licensing to the original contractor for a sharply limited period when deemed desirable to expedite production. It should additionally be said that the failure to identify the broader issues, and compel their attention at the Secretary's level, before the Service became enmeshed in the details of contract negotiations, meant the loss of opportunities for agreements more defensible from the standpoint of public policy. As the exigencies of the situation developed, it was the Department, rather than the drug companies, which was "on the spot."

This struggle surrounding the cancer chemotherapy program should not, however, obscure the fact that the standard policy of the Department is operating in the contract as well as other fields. Testimony before the Subcommittee on Monopoly of the Senate Small Business Committee in December 1959 stated that—

> whereas a total of 227 research contracts were entered into by the Public Health Service during the fiscal years 1958 and 1959, under the cancer chemotherapy exception less than 15 contracts were executed which left invention rights to the contractors.[58]

Despite misgivings on the part of industrial concerns and others, the role of the Federal Government in conducting and assisting research is irresistibly expanding. This development is inevitably accompanied by concern for the wide availability and use of the inventive product of research and the prevention of its monopolistic exploitation. This concern is particularly great in the field of health where breakthroughs in science hold promise of worldwide conquests of many of the diseases that plague mankind.

The Department's policy, with respect to inventions and patents, has been developed in the light of its statutory responsibilities for health, education, and welfare and for dissemination of the results of

[56] For discussion, see Rose, S. K., "Some Patent Aspects of the Conquest of Cancer" (1959). This paper is not yet ready for publication but is available for examination at the Patent, Trademark, and Copyright Foundation of the George Washington University Building. On patents as a factor in the economic position of certain drug companies, see "Economic Report on Antibiotics Manufacturers," supra, note 54.

[57] House Committee on Appropriations, Rept. 217 to accompany H.R. 6287, 85th Cong., 1958, p. 19; Senate Appropriations Committee report on same, pp. 22–23.

"* * * the committee considers that progress in making industrial contracts has been unnecessarily slow. The committee directs that utilization of industrial facilities for this program be expedited * * *" (S. Rpt. 416, 85th Cong., 1st sess., p. 23).

[58] Statement by Parke M. Banta, General Counsel, Department of Health, Education, and Welfare, Dec. 9, 1959.

research. The issues have been beclouded by outmoded personnel practices and absorption with the complexities of the patent system as such. The following pages analyze, on the basis of experience in the Department, some of the many facets of the problem and suggest the outlines of a simpler, freer approach geared to the objectives of Government research in the health and welfare field.

B. Basic Policy Questions

1. INVENTIONS OF GOVERNMENT EMPLOYEES

(*a*) *Patents as a matter of prestige or monetary award*

Is it necessary or desirable, in order to command the best effort of employees, to hold out to them as a matter of prestige or monetary reward the patenting of inventions made in connection with their work? [59]

This is the question in the patent field which lies closest to the aims of the mounting research programs of the Department, all of which depend on the alertness and zeal of the employees engaged in them, not only of the top scientists but of the supporting technical staffs representing a wide variety of skills. It is the question also which lies closest to the constitutional purpose of the congressional power to provide for patents in order—

> to promote the progress of science and useful arts, by securing for limited times to * * * inventors the exclusive right to their * * * discoveries.

To this question the Department has given a negative reply. Has Department experience borne out the soundness of its position?

At this point it may be well to recall the basic legal position in the absence of a controlling policy. The entire right, title, and interest in an invention made by an employee within the scope of his specific assignment to invent belong in equity to the United States; if the invention lies outside his assignment the Government is at most entitled to a shopright. As *Dubilier* has stated, the Government in this respect stands in the same relation to its employee as any other employer would stand; all depends upon the bargain between them, express or implied. Proposals have been made for legislation which would leave the Government employee all rights (except in inventions developed pursuant to specific assignment to make the invention) subject to a license to the Government if there had been a substantial Government contribution to its making or development.[60] On the other hand it has not, I believe, been seriously suggested that an invention of a Government employee which is unrelated to his work and made without a contribution of Government funds, work-

[59] The phrase "inventions made in connection with their work" is here used in a broad sense. The degree of relationship to official duties and specific assignments necessary to support required assignment are discussed elsewhere.

[60] Finnegan and Pogue, "Federal Employee Invention Rights—Time To Legislate," 55 Mich. L.R. 903 (1957).

ing time, equipment or facilities should be subject to required assignment or even required license to the Government.[61]

The question, therefore, as tested in practice within the Department, relates to motivation, to that subtle ingredient which stimulates the inventive wits of man. The motivation, so far as patents are concerned, involves in most cases only factors of prestige and recognition. To the extent that either domestic or foreign rights may be left to the inventor, it involves also the possibility of profitable exploitation.

In connection with this study effort has been made, both by personal interview and examination of individual case files, to ascertain the reaction of affected employees to the present policy. The problems of inquiry are heightened because, although awareness of the policy is growing, the fact of invention frequently finds both the scientist and his immediate supervisors quite uninformed about Department regulations but full of ideas as to what should or should not be done patentwise. Very often, for these are workers who live in an atmosphere and tradition of public service, these ideas are founded on what the inventor conceives to be the best method of protecting the interest of the Government. It is often difficult, for this reason to disentangle and identify the concept of private interest in an invention from that of the Government or the public.

(1) *Food and Drug Administration.*—Experience in the Food and Drug Administration illustrates the persistence of this difficulty. In this agency there had been a long tradition under the Department of Agriculture of invocation of the nonfee statute for so-called public service patents, coupled with assignment to the United States of the domestic rights. Employees understood that patenting was the method preferred by the Government for the protection of the inventive product of its research work and the alternative of publication had no place in the established routine. An inevitable byproduct of the routine was the burdening of administrative and legal channels with patent applications, some of them of questionable merit. Thus the chief of a division reporting to the Commissioner concerning a device of doubtful patentability remarked that—

> our purpose in proposing that we secure a public service patent was to prevent exploitation of the public through commercialization of the device.[62]

Following the issuance of Executive Order 9865 relative to the obtaining of foreign rights "wherever practicable" on inventions resulting from Government-financed research, the Food and Drug Administration was asked by the Federal Security Agency to report any patents issued on applications filed since the date of the order. It developed that two patents had been issued in the name of the inventor on variations of measuring instruments, with assignment of the domestic rights to the United States and retention of foreign rights by the inventor, according to the usual practice. The inventor, how-

[61] One determination by the Surgeon General, in 1958, is to the contrary. Government Patents Board, GPB 6–64. Determination that the Government is entitled to a license in such a case was apparently based upon the around-the-clock theory of the duty status of the inventor, an officer in the Commissioned Corps of the Service. There was no appeal by the employee in this case. The Department, however, concurred with the ruling of the chairman of the Government Patents Board that the Government was not entitled to a license.

[62] Memorandum of John Harvey, Chief, Western Division, dated Sept. 29, 1942, re invention of Dr. Meuron.

ever, was reported to be entirely willing to assign the foreign rights also to the Government.[63]

The first determination under Executive Order 10096 and Federal Security Agency order 110 which involved an invention report from the Food and Drug Administration involved a modest but useful device to prevent waste of feed by small laboratory animals. The invention was made by two laboratory workers who observed the need while engaged in official duties but who worked it out on their own time and without a contribution of Government materials. In their report the inventors said a patent would be in the public interest since at least the Government would have the means available of controlling manufacture and saving itself money; they made no personal claim. This was one of the cases transmitted to the Department of Justice for a patent application under the nonfee statute with a reservation of a license to the Government; it was returned to the Federal Security Agency when the Department of Justice discontinued its services to Federal agencies in the preparation and filing of patent applications. The Federal Security Agency decided not to prosecute the application although the inventors were free to do so. Meanwhile the Chairman of the Government Patents Board pronounced that the Government was not entitled to a license by reason of Executive Order 10096 standing alone, a conclusion with which the Agency had no quarrel.[64] The patent officer of the Agency then prepared a memorandum of explanation on the entire situation, and the last note in the file on this momentous case (which had occupied the attention of three independent Government agencies) is a report that the inventors—

understand the situation completely but still prefer to give the Government a royalty-free license on any patent which may issue.

Significant inventive developments in the Food and Drug Administration in recent years have centered in the Division of Antibiotics, the Division charged with the testing and certification of penicillin and other antibiotics. In the period 1947–49 six patents were issued in the name of the inventor, Dr. Henry A. Welch, who was then (and up to the time of writing this report was still) the Director of the Division. It had been Dr. Welch's practice to retain a private attorney to prepare and file the application papers on these inventions, which included important therapeutic compounds. Later, according to practice, an assignment of all domestic rights was made to the United States, the foreign rights being left to the inventor. The foreign rights were in some cases disposed of to certain American drug companies by the inventor for a substantial consideration.

The Welch inventions represented situations in which the Government would have been entitled to the entire right under the Executive order but, as a memorandum of the Commissioner records,[65] the prosecution of foreign patent rights and the policing of them was too expensive and onerous for the Government. It was found, however, that the purchase of foreign rights from the inventor by certain companies gave rise to fears on the part of others that the impartiality of the Food and Drug Administration in the administration of its certi-

[63] Memorandum of Oct. 17, 1947, to A. J. Buscheck, Office of the General Counsel, regarding Patents 2,355,406 and 2,381,414: Dr. John Wilkins, inventor. On a third application which was still pending, the inventor was unavailable for report.
[64] Government Patents Board, GPB 6–38. These decisions are not published.
[65] Commissioner Dunbar, memorandum to files, Mar. 30, 1950.

fication services might be impaired. It has been a jealously guarded policy of the Administration that none of its employees who has any part in making policies or in enforcement operations should have any financial interest or receive income from any firm whose business or whose sale of commodities is subject to laws enforced by the Administration. In keeping with this policy Dr. Welch was asked to make, and did make, a dedication of foreign rights to the public insofar as he still retained such rights.

Interviewed as to present policies, Dr. Welch indicated that on inventive developments he would in the old days have filed a patent application but that now there was no incentive to patent since, unless an employee could get some return from foreign rights, he could not afford to go to all the effort involved in working up the details of a patent application, an elaborate and exhausting process. He approved, however, the alternative of publication as a matter of Government policy, with its avoidance of the complexities of the pursuit of patent rights, the utility of which, he commented, is increasingly doubted by some private concerns. On one point, and the one here at issue, he was emphatic: the inventive talents of the research worker in Government will not be stilled, and they are not at all dependent upon the patent incentive. Dr. Welch was himself in 1954 the recipent of a Distinguished Service Award from the Department. It would be absurd to think of such an award as other than honorary recognition for achievement in a field which contains its own challenge for the pursuit of invention and knowledge.

The cash award system operates on a different level from the honorary awards for highest achievement; nevertheless, the individual who is keen on his work is more likely to attach greater significance to the post facto recognition that it provides than to its specific incentive or material reward. Thus, a current example of the exercise of inventive talent in the Food and Drug Administration consists of a new method for the production of penicillinase, used in laboratory testing for the rapid inactivation of penicillin. The two inventors are bacteriologists in the Sterility Testing Branch of the Division of Antibiotics. They were recommended for, and received, cash awards of $200 each under the employee award system. The recommendation for the award noted three points: That the process has resulted in tangible monetary savings to the Government, that it has developed a better product, with potency and sterility assured, and that the inventors had demonstrated alertness in applying current scientific developments. Technical publication is now in course of preparation which will make the benefit of the new knowledge available to all.

(2) *Public Health Service—Bureau of State Services.*—In the Public Health Service, inquiry has involved the National Institutes of Health, in which the bulk of research activity is centered, and the research establishments under the Bureau of State Services which include the Communicable Disease Center at Atlanta, the Robert E. Taft Sanitary Engineering Center in Cincinnati, and the Occupational Health Field Headquarters in the same city.

The files of the Bureau of State Services show 13 invention reports from the Communicable Disease Center and its affiliated stations in the period 1949–59. The inventions were the direct outgrowth of work in the laboratories of the Center and in no case was there a claim of

personal interest. Prior to the adoption of a specific patent policy by the Federal Security Agency, the practice was to receive invention reports as requests for patenting under the nonfee statute and for the purpose of protecting the interests of the Government. After reference to the Department of Justice no less than eight of these were dropped for various reasons. Either patentability was doubtful because the invention was covered by the prior art or because there had been publication of more than a year standing, or it was felt that the interests of the Government would be sufficiently protected by publication; one application was dropped after initial rejection by the Patent Office. The record at that time shows that the Chief of the Patent Section in the Department of Justice was troubled by the number of requests for patent actions on inventions of dubious patentability and importance, and that the Chief of the Bureau of State Services in the Public Health Service was seeking advice as to how the Government interest might be protected in those instances where there is administrative doubt as to the significance of a device or the necessity for securing a patent.[66]

On one application filed in this period a patent was allowed on an insecticide composition, a field in which the Communicable Disease Center was and is actively engaged.[67] This was an assignment case, like the others, with procedures geared, however, to the nonfee statute. The first determination under Executive Order 10096 and Federal Security Agency order 110 was also processed to the issuance of a patent, the invention in this case being a procedure for the preparation of certain types of chemicals.[68] The second, involving new insecticidal combinations, was pressed to the point of patent application and rejection by the Patent Office. Again there was no claim of personal interest and the Bureau of State Services queried more persistently than before whether the objectives of its tax-supported research would not in general be adequately served by publication.

In contrast procedurally, after the declared policy in favor of publication had crystallized, was a notable invention of "DDVT-beta substituted alpha keto phosphates." This was a compound with outstanding insecticidal properties useful in the fields of both public health and agriculture. It was developed at the Technical Development Laboratories of CDC at Savannah. The inventors did not question the Government's right to assignment but recommended both domestic and foreign patenting; if the Government chose not to exercise its option to acquire the foreign rights, they requested that such rights be left to them. The determination was for assignment of the domestic rights and for dedication by publication.[69] Technical publication was supplemented in this case by a number of special mimeographed announcements designed to take care of the mounting flood of requests for information from industry and potential users.

Foreign rights in this case were left to the three inventors, and the Office of Technical Services in the Department of Commerce offered

[66] Letter dated May 25, 1950, from Roy Hackley to Communicable Disease Center; memorandum, Dr. C. L. Williams, director, Bureau of State Services, to Assistant General Counsel, Federal Security Agency, June 15, 1950.

[67] Patent No. 2,572,864, "Pine-Gun Rosin DDT Insecticide Composition." Inventors, Summerford and Jensin.

[68] Patent No. 2,653,160, "Preparation or Organometallic Compounds in Organic Solvents." Inventors, Doak and Freedman.

[69] The determination to rely on publication concurred in by the Chairman, Government Patents Board. GPB 6–45.

assistance in their utilization. Assignment of the foreign rights was made to the Grace Chemical Co., for a fixed amount, plus a share in receipts from foreign patents should these be realized.

The inventors in a written comment to the writer [70] state their belief that, wherever warranted, the Federal Government should obtain patent rights on an assignment basis as—

> this recognition as a patentee may be the only public acknowledgment of the inventor's work.

They further believe the granting to inventors of the right to seek foreign patents is most desirable:

> For the inventor it serves as a stimulus not only to gain recognition but to obtain unexpected remuneration. This would have the effect of attracting better personnel to Government service in all fields.

The inventors' judgment here is necessarily speculative and the officers of the Communicable Disease Center do not share the view that the possibility of "unexpected remuneration" through patents would have the effect of attracting better personnel to Government service in view of the incentives now offered.

In the venereal disease experimental laboratory in North Carolina, a field station of the Communicable Disease Center, Dr. Joseph Portnoy developed and reported in 1955 the invention of "a process for preparing a serologically active fraction of virulent treponema pallidum." This offered a simple, easy-to-perform complement fixation test for the serodiagnosis of syphilis; it had great potential values both for military and civilian control programs. Patenting was recommended in order that there might exist an effective means of controlling the quality of the chemical fraction as a diagnostic reagent, it having been ascertained that the control program of the Public Health Service and of the Food and Drug Administration did not adequately cover the need for quality control. A patent was accordingly sought and obtained.[71] Dr. Portnoy in 1959 received the Distinguished Service Award from the Department not because he had made an invention which was patentable, but "for outstanding contributions to venereal disease control, including the development of the rapid plasma reagin test and the treponema pallidum complement fixation test for syphilis."

Within the Center a number of employees, particularly those in the vector control programs, had formerly been employed in the Department of Agriculture and were familiar with its procedures. The Chief of the Technology Branch expressed a preference for the Agriculture procedure under which inventions went quickly to a patent attorney in the Department and were processed through the Patent Office, the ensuing patent being assigned to the United States. He spoke of one employee whose office was adorned with copies of letters patent on inventions made while in Government employ and on which the rights had been assigned to the United States; the display was a source of gratification and pride to the employee. The Chief, however, expressed the view that, from the employee and the field office standpoint, the matter of patenting is not of prime importance so long as

[70] Letter of Sept. 8, 1959, to the writer from George W. Pearce, Janet Spillane, and Arnold Mattson.
[71] Patent No. 2,892,755.

the procedure of report and determination is simple and clear. Incidentally he was skeptical of the value of the employee award system for men of scientific stature.

The Director of the Communicable Disease Center, Dr. Robert Anderson, interviewed at Atlanta, indicated that although he had little direct experience with patent questions he had brought to his post in 1956 a conviction that "what the public develops the public should have." His viewpoint had been strengthened by growing acquaintance with the nature of research efforts and research groups.

At the Robert E. Taft Sanitary Engineering Center the assistant director was interviewed. He characterized the incentive award system as taking a lot of time, concluded that the good scientific worker does not need this type of stimulus. Collecting patents at Government expense would make a fine record for the employee and would be a help to the employee in seeking outside employment (better even, in his opinion, than a record of scientific publication) but would not be significant otherwise. Scientists, in his observation, feel strongly that there should be publication of their work in scientific journals, of their own choosing, and at the time of their choosing. In this sense the scientist does have a proprietary feeling about his work, and this is a real problem because disclosure of results should sometimes be made before the scientist is fully prepared to report, in order that through publication the opportunity for work on the problem may be opened up to others and progress be thus quickened

There have been three complete reports of inventions from the Center. On one, patentability had already lapsed because of prior publication. On two others, it was determined, and the inventors agreed, that the Government was entitled to assignment but that dedication by publication would be sufficient to protect the public interest.[72]

The Occupational Health Field Headquarters at Cincinnati provides technical assistance to State and local health departments and industrial hygiene agencies. It does a great deal in the improvement of instruments purchased from others and conducts tests of the diagnostic and analytical methods of such agencies. According to the director, the patent policy of the Department presents no problem: scientists at this station regularly write up technical descriptions which are adequate for disclosure purposes, and publication is relied upon for protection. To date, he continued, there have been no patents on inventions developed at this particular station; if a basic device were developed, patenting would be recommended in the public interest.[73] The occupational health group in Cincinnati is one of close-working association with small turnover of personnel. It has particularly prized the type of award presented to it by the American Medical Association in a certificate of merit for sustained program activity in contributions to public health rendered by the whole group over a long period.

(3) *Public Health Service—National Institutes of Health.*—The principal research arm of the Public Health Service is, of course, the National Institutes of Health, the great research center at Bethesda,

[72] Determination to rely on publication concurred in. GPB 6–56 and 6–59.
[73] It was, however, from the work of this branch of the Service that there developed the fumigant gas which was involved in the *Houghton* case.

Md., with its several Institutes,[74] its Clinical Center, and its divisions of General Medical Services, Biological Standards, and Research Grants.

Since the inception of a central patent policy by the Federal Security Agency, the Institutes have had in the Research Grants Division administrative machinery for handling invention and patent matters, both in connection with grants and for employee inventions. Unfortunately the Institutes have failed to develop procedures adequate to inform all members of their research staffs of the existence of the policy and the reasons therefor. Also, instead of requesting a clear-cut statement of the inventor's legal claim, if any, in the invention (as is provided in the Department form for "Report of Invention"[75]) the Institutes have used a modified form which simply lists as one item on which information is sought: "10. Your personal desires on applying for a patent on the discovery."

As might be expected, a check of responses to this item (which was made for the period July 1, 1956, to July 1, 1959) shows very diverse and frequently ambiguous replies. Samples are:

1. I have been advised that this method should be patented.
2. Possible monetary gain.
3. To protect both mine and the public interest.
4. Desire patent rights of the Government does not elect to obtain title (Executive Order 10096).
5. To protect the discovery of NIH. Might be profitable for PHS and Government to obtain royalty-free purchase.
6. Would be content with publication.
7. To insure wide-scale commercial availability. (No personal claim.)
8. Would like recognition by publication for an original contribution to the art. The only reason for a patent so far as I am concerned is to somewhat augment my salary so that I can continue in my present work which I very much enjoy.
9. To preserve our identification with the discovery and to make it available to the public.
10. Patent recommended as important (1) as a protective device pending clinical testing, (2) because field is highly competitive, (3) to control the product (a dangerous drug). No personal claim.

Nos. 7 and 10 are typical examples of different types of inventions and of employee attitudes.

No. 7 consisted of a "disposal plastic paraffin embedding tray," useful in laboratory work as a lightweight container in which pathological specimens can be seen. It was made by a biologist in the Medical Art Section of the National Institutes of Health and, although at least one commercial company had made inquiries about it as a prospect for manufacture, its patentability was somewhat in doubt. The determination was that the Government was entitled to the full right but that publication was adequate to protect the public interest; the inventor might patent if he so chose, subject to the requirement of assignment to the Government.[76] Many requests have been received for a reprint of the publication which was made in Government research reports. The inventor has been recommended for and has re-

[74] National Cancer Institute, National Heart Institute, National Mental Health Institute, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Metabolic Diseases, National Institute of Dental Research, National Institute of Neurological Diseases and Blindness.

[75] Health, Education, and Welfare Manual Guide—General Administration, "Patents and Inventions." (Appendix C, infra, p. 70.)

[76] The Chairman of the Government Patents Board concurred in the determination to publish without patenting.

ceived $100 as a cash award under the employees' incentive awards program. Interviewed, the inventor indicated that he had no complaint with this handling of the invention nor with the patent policy of the Department in general. Of course, he said, it would be nice to have a patent just to have a patent, but to be practicable this way is OK; and the invention clearly is one which belongs to the Government.

No. 10 involves a highly important and complex analgesic or pain killing product which represents the culmination of years of research by Drs. Everett May and Nathan Eddy in the laboratory of the National Institutes of Health, with clinical testing both within and without the Institutes. The importance of the drug lies in the fact that it is relatively nonhabit forming and that, although not a morphine, it is a narcotic and as such is subject to obligations of control under treaties to which the United States is a party. While making no personal claim the inventors recommended patenting in the public interest. The Department is agreed that publication is insufficient in this case for various reasons and patent application is in progress [77] following assignment of the domestic (and later the foreign rights) to the United States. A very large file on the various problems presented by this invention indicates on the part of the inventors only a total preoccupation with solutions which would serve the public interest, with no suggestion of interest in possible benefits that might accrue to them personally through patenting.

Notwithstanding the lack of understanding of Department policy reflected in many invention reports, the assertion of employee rights as against the Government or the public has been slight. The records of the Department show but two cases of appeal from final determinations that the Government was entitled to the entire rights. Both of these involved employees at the National Institutes of Health, and both represented dissatisfaction with the declared policy. One of these involved the question of monetary reward, through ownership of patent rights, the other the question of honorary recognition through patenting. Only the first case involved appeal to the Chairman of the Government Patents Board.

The first case involves the invention of a tangent screen for visual fields made by a physicist in the Opthalmology Branch of the National Institute of Neurological Diseases and Blindness. The inventor at the time of making his invention had engaged an attorney to handle his claim for full rights in the invention subject only to a license to the Government; assistance of the Government was requested in preparing and prosecuting the patent application. The determination was that the Government was entitled to the entire right and that the Government interest would be met by publication; the probability of appeal was noted and quickly materialized. The inventor relied largely on a claimed separation between his work on physical optics, in which he admittedly was employed to exercise originality and inventive faculties, and his work in clinical optics from which the invention had developed.

The case was significant and important for two reasons. First, it presented the legal question of the extent to which the void in predeclared administrative policy which had proved fatal to the Gov-

[77] Serial No. 771,165. GPB–6.60.

ernment in the *Dubilier* case, had been filled by the Executive Order and Agency order 110. This question was not decided in the appeal proceedings. Second, from the standpoint of policy it involved for the National Institutes of Health the entire concept of an integrated research effort, a concept of prime importance to its overall objectives.

The policy issue had been presented by the Department to the Chairman of the Government Patents Board in these terms:

> These combined Institutes constitute one of the largest centers in the world devoted primarily to research, both laboratory and clinical, in the field of health. The Clinical Center, within the Institutes, is devoted entirely to research. Its scientific and professional personnel are in effect a team brought together solely for the purpose of seeking in the public interest better methods of preventing, diagnosing, and treating the diseases of man. It is to be expected that important inventive advances, many of them patentable, will arise as a natural product of such an institution and, as a matter of policy, that the full product of the public investment in the institution will be preserved for the public benefit.[78]

Following a factfinding inquiry at which the inventor appeared with his attorney the Chairman of the Government Patents Board upheld the determination of the Department.[79] He found that the facts did not support the separation of official duties claimed by the inventor and noted particularly the purpose and nature of the Clinical Center, which is—

> a medical research center staffed by selected personnel of the type of the inventor and combines both laboratory research and related clinical functions.

This inventor is still employed at the National Institutes of Health, and instruments based upon his invention as published in opthalmological journals are being manufactured by a number of companies. The policy applied has not acted as a deterrent to his continuing work in Government employ which offers other compensations. Interviewed on the point, however, he remains of the opinion that for some types of employees, particularly those who are "gadgeteers at heart" the possibility of patenting with the opportunity for monetary return through royalties would be a stimulant to invention.

The second case, which arose in 1958, involved the invention of "a bridge circuit for temperature measurement with semiconductors," a combination of several kinds of electrical devices in an arrangement by which the instrument can measure temperatures simply and accurately. The inventor is a scientist of standing and Chief of the Laboratory of Biophysics of one of the National Institutes. Notwithstanding his view that patenting was desirable to insure the quality of the device, under restricted licenses, the determination was that the Government was entitled to the entire right but that publication would suffice to protect the public interest. The inventor was dissatisfied with this result and the circumstances of the case were such that the Department Patents Board made it the subject of a policy review.

This was a special review after the period for the taking of appeal as provided by the regulations had lapsed and after the Chairman of the Government Patents Board had agreed with the De-

[78] Department memorandum to Dr. Archie Palmer, Chairman, Government Patents Board, May 18, 1955.
[79] GPB 6–48.

partment's determination that the public interest did not require patenting and would be met by the publication already made in "The Review of Scientific Instruments." [80]

In the inventor's memorandum prepared for the purpose of review by the Department Patents Board, his comment on the point of employee recognition was as follows:

> I understand that under certain circumstances the results of medical research should be protected by means of scientific publication, but I am concerned when inventions of the type that would actually be recognized by patent protection in a university or industrial environment, that the Government does not find a way to patent such inventions. The issuance of a patent is in my opinion a nonremunerative recognition of the work of scientists who choose Government as a career; furthermore, I am of the opinion that a policy favoring publication as a means of protecting Government interests discourages the exercise of creative imagination and initiative of those individuals with "inventive" minds who hold Government jobs.

This comment reflects the extent to which patents have come to be regarded by some employees as a form of honorary recognition. If this inventor's views were widely shared, the Department's policy in favor of dedication by publication, rather than patenting, could present a problem from the standpoint of personnel policy. As it is, the case points chiefly to the need of wider advance understanding of policy among its research workers and a clarification of procedures in the handling of individual cases.

An illustration of a unit in which policy is well understood and implemented is the Instrument Section Laboratory which services all the Institutes. This section now fashions in the course of a year as many as 4,000 instruments, unavailable in the general market, which are required by physicians and other scientists in the course of their researches.[81] Some of these instruments are duplicates but some 60 percent are new, and many of them are on the line of useful new discovery. When there is indication of extensive outside need or use, technical publication is made for the purpose of disclosure and for the protection of public right in the invention. There have been 100 such technical publications during the 22-year life of the section. When there has been no such publication and request is made for duplication of the instrument upon order for a nonprofit institution, drawings and designs are furnished to the institution upon execution of a simple acknowledgment form to the effect that the technique was developed at Government expense for public use and that all rights thereto remain the property of the Federal Government. When, as frequently happens, commercial firms request the drawings and designs for commercial production, another form of acknowledgment is used, with publication references, as a safeguard against subsequent claims of exclusive right. The present policy favoring technical publication is well understood and accepted. (See appendix I, p. 90.)

Conclusion

(Except as otherwise indicated, the conclusions here stated, as well as those on other points which follow, are those of the writer. They are offered on the basis of the admittedly limited experience

[80] GPB 6–58.
[81] Interview with Laurence Crisp, Chief, Instrument Section, Laboratory Aids Branch, Division of Research Services, August 1959.

of the Department of Health, Education, and Welfare and the observation of policies still in a process of evolution. Perhaps they should be described as "propositions" rather than conclusions. Their value, such as it may be, lies in the fact that they represent a fresh look at a very old system in a research setting which is significant and new.)

The prosecution at public expense of patent applications has no place as an instrument of personnel policy.[82] This is particularly true in respect of employee inventions in the field of research oriented to the public welfare.

The collaborative approach to research problems in the modern planning staff or laboratory makes the use of patents as a means of honorary or monetary award to employees a potentially divisive force. The difficulty of identifying and isolating the inventor in an atmosphere in which ideas, suggestions, contributions, and discussion are and should be widely shared, increases the danger. If patentable invention is deliberately pursued it may warp and distort the course of the research.

As a method of honorary reward, it is inappropriate. A patent is essentially an economic instrument, and intended to be such; it derives its significance from the power to exclude others from the use of an invention and thus to exploit it as property. To use the patent system as a means of gratification to the inventor's pride, as has often been the case, is to use the system for purposes for which it was never intended and to place undue burdens upon the Patent Office.

As a means of attracting and retaining the services of scientists of competence and brilliance in Government research, the results of which must be dedicated to the general benefit, the prosecution of patent applications as a form of reward for employee accomplishments is simply not enough.

Under prevailing patterns the research worker in industry is bound by tight contractual provisions to yield to his employer the products of his research. But it has been urged that since Government service is not highly paid or rewarded, the employee should be recruited and enticed to remain by the chance of profitable exploitation of patent rights in inventions growing out of his public employment. Even if the contention were otherwise valid, the situation on which it is premised is changing substantially. Modern personnel systems in Government now deal broadly with both the material and the psychological factors which make employment attractive or unattractive

On the material side, Government employment in general has been made more attractive by pay raises and the increasing provision of fringe benefits such as employees compensation, retirement benefits, and life insurance, to which health insurance has been added by the present Congress. In addition, special provisions apply to scientific positions; for example, legislation which provides for fixing entrance salaries above the entrance level for the grade applies to hard-to-fill positions in the scientific and professional areas. This increases the number of authorized scientific and professional positions in the Public Health Service for salaries in the range of $16,000

[82] The nonfee statute provides only for the waiver of Patent Office fees in those cases where the head of an agency finds that the invention is liable to be used in the public interest.

to $19,000 may be fixed and which authorizes additional supergrade positions throughout the Government service, in which those in scientific and professional positions share.[83]

On the psychological side, the Federal employees incentive awards program operates to supply forms of honorary award for careers, or for individual or group actions, of outstanding or superior distinction. It also offers cash awards for meritorious suggestions, work performance, or special acts or services. It is perhaps unfortunate that members of the commissioned corps of the Public Health Service, which is a career system modeled closely upon the military, are not covered by the awards program; they are, however, expected to have a comparable program of their own.

The present provisions may be inadequate to attract and hold sufficient personnel of high caliber in Government service. It is, however, upon provisions such as these that the inducements to satisfaction in Government service must be built. The offchance of profit from royalties on inventions developed, in greater or lesser part, with Government resources, can rarely be a determinant factor; and if it were, in any case, the determinant factor, the suitability of the worker for research conducted in the public interest would be seriously in question.

Granted that the first responsibility and interest of most employees, whether dedicated research workers or others, is to make a satisfactory living and to provide for the future, the motivation which impels the research worker to his best efforts, in Government or elsewhere, is basically the compulsion of the scientific spirit itself, the seeking of new knowledge in the conviction that what is discovered must in the end be of benefit to mankind or must, at least, be known in order that it may be dealt with. The working environment is of high importance, varying according to individual personality, but generally assured in terms of the general field of exploration, scientific freedom, stimulating associations, physical equipment adequate to the research endeavor, and a ready outlet for the results of the research to be widely known and availed of. The channels of technical publication are especially important, serving as they do both the needs of the research effort itself and as a record of the scientist's own achievements among his peers. Among the imponderables, the concept of public service constitutes for many Government employees a motivation as strong as it is frequently underrated. In the fields of this Department the motivation of service to human welfare is a very definite factor.

(b) Research and nonresearch workers distinguished

What distinction, if any, should be drawn in this respect between the research and the nonresearch worker?

It is obvious that the securing of a patent as a form of honorary employee award, while its economic significance is destroyed by assignment to the Government, is equally an abuse of the patent system regardless of whether the worker is or is not directly engaged in research. Whether the invention should be left to the nonresearch worker in order that he may exploit it commercially is a question of law and equity under Executive Order 10096 and the Department regulations but it also touches upon a question of personnel policy.

[83] 5 U.S.C. 1135; 42 U.S.C. 210(g).

Inventive talent is not limited to the research worker or to those in shops and laboratories whose function it is to fashion instruments and devices needed by the scientists to conduct their work most effectively. It is latent in many a worker whose official duties are far removed from scientific pursuits and who is stimulated to activity simply by needs observed in the course of the performance of routine tasks. Thus the watchman invents a lock, the animal-house attendant invents a new feeding device, the employee who handles exhibits invents a new type of holder for their display, the electrician invents a new type of floor plug extractor, and the hospital mechanic invents a bottle collar remover.

It is not a part of the basic bargain of the Government with such an employee that he should exercise inventive ingenuity or push back the horizons of science or improve the mechanics of humble devices. Whether or not the employee develops the concept of an improvement which occurs to him in the course of his work may very well depend upon the stimulus of a possible monetary or other award. Executive Order 10096, and the Department regulations conforming thereto, set a reasonable approach for distingishing such a situation from that of the employee who is hired to conduct or perform research or development, or to supervise or review such work. In the case of employees in the latter group the presumption is that the Government is entitled to the entire right; in the case of employees not connected with research the presumption is that the Government's contribution is "insufficient equitably to justify a requirement of assignment." [84] Either presumption may be rebutted by the circumstances under which the particular invention is made.

Much of the difficulty in the application of the Order and regulations lies in confusion of the principles to be followed in determining the validity of the presumption in a particular case. It is believed that the only sound test lies in ascertaining, in a broad sense, the bargain between the employer and the employee as indicated by the immediate circumstances. The terms of that bargain may be expressed or implied. Job sheets are useful evidence of the scope of official duties; they are far from representing the actual circumstances of the employee's work in all instances.

The nonresearch employee may bring an inventive concept into his place of employment and may be allowed, as a matter of accommodation, some use of Government facilities and equipment without creating more than a shop right in the Government. If he is additionally permitted to use his working time on the project, supplanting the performance of his regular duties, the project becomes an undertaking of the Government and the employee's effort a part of his work. This may not exclude a bargain at the threshold whereby the employee, with a concept developed entirely apart from his official duties, seeks its development to the point of reduction to practice, and the Government as the employer undertakes work on the project in return for a shop right only. But where the Government is the employer, and the employer's interest, therefore, is that of public service rather than a narrowly proprietary interest, only a very specific agreement should be taken as evidence that the Government intended to expend Gov-

[84] Executive Order 10096, secs. 1(b) and 1(c). See in Department regulations, sec. 7.3(b). (Appendix B, infra, p. 70.)

ernment time, money, and resources on the research, the results of which would become, save for a license to the Government, the property of its own employee.

Where the employee's concept is itself the direct outgrowth of his work, or in the words of the Executive order "bears a direct relation to or is made in consequence of the official duties of the inventor" there is no room for an arm's length bargain between the two. It is perhaps said too often that the nonresearch employee is under no obligation to exercise his inventive faculties for the Government. He is, however, at least a poor employee who does not exercise his wits on his job. At any rate if he does exercise them in an on-the-job connection and if the Government proceeds to develop the concept with a substantial contribution of its own resources, the requirements of equitable assignment, as specified by section 1(a) of the Executive Order, are satisfied.

Nor is there room, when the Government has devoted time and resources in the making of an invention, to invoke the notion of "insufficient interest" in the perfected results for the purpose of disclaiming ownership. "Insufficient interest," provided for in the Executive Order, is like a hole in the bag which permits the abandonment of public ownership on a basis for which almost no criteria are available and without congressional authorization. Its presence in the Order is perhaps due to the many situations in which the Government does not feel warranted in going to the burden and expense of prosecuting a patent application. But the question of how ownership of an invention should be protected, if at all, whether by patenting or publication, is quite different from a decision to renounce the Government's ownership rights. There is no area in which the application of the Executive Order has been more confused than in this, and the Department's determinations are not free of such confusion.[85]

Relatively minor from the standpoint of patent policy or research objectives, and not likely to be of great monetary consequence to the employee, the handling of such cases is important from the standpoint of the consistent application of equitable principles and of employee morale. To the employee who has shown ingenuity and initiative a determination of "insufficient interest" under the patent policy is likely to be a wounding jolt, and a discouragement to further creative interest in his work and the reporting of inventive and other ideas. These are cases for which the incentive awards program is particularly appropriate as a stimulus and as a means of recognition.

[85] Thus, when a machinist at a Public Health Service hospital conceived and constructed a model lock to meet a need observed in his work and constructed it in off-duty hours using a slight amount of Government materials, the Government contribution was held insufficient to require more than a license (GPB 6–55); when the chief of the animal section in a Food and Drug Administration laboratory, during working hours and in connection with his work, invented a food dispenser for small animals, it was held that the Government was entitled to the entire right (changed to a license only when it developed that the invention had been made before Executive Order 10096) (GPB 6–14): when draftsmen in the Social Security Administration invented, in connection with their work and during working hours, a modification of a duplicating process, it was held that the Government was entitled to the entire right (GPB 6–34); when the electrician at the Clinical Center invented, during working hours, an extractor for an underfloor wiring system, *held* Government, though entitled to an assignment, has "insufficient interest" to acquire more than a license (GPB 6–39); when a general mechanic employed at a PHS hospital, prompted by a need observed in his work, invented a bottle-collar remover during working hours and with the use of Government materials, *held* Government entitled to an assignment, but interest insufficient to require more than a license (GPB 6–55); the Chairman of GPB in this case disagreed with the ground of the Department's decision and held the Government not entitled to an assignment because the invention did not bear a relation to the inventor's work.

Coupled with publication in a technical magazine a cash or superior service award can give a sense of pride in sharing with other employees the satisfaction of contribution to the public service. In the assessment of motivation in Government, employee satisfaction of this nature is not to be underrated, and should be cultivated.

Conclusion

No distinction in principle should be drawn between the research and nonresearch worker, although there is room for a rebuttable presumption that in the case of the nonresearch worker an invention is not directly related to his work and that the Government has not contributed substantially thereto. When the employee is permitted to use his working time on the project, supplanting the performance of his regular duties, it cannot be said that such use of time is not directly related to his work.

Determination of the respective rights, in law and equity, of the Government and the employee in an invention is a judicial or quasi-judicial function, involving the circumstances which gave rise to the invention. Whether, if the Government is entitled to an assignment, steps should be taken, by patenting or otherwise, to protect its interest is a separate and subsequent question; the fact that the Government, for "insufficient interest" or other reasons, may decide not to patent should have no bearing on the determination of rights. When the Government is entitled to the rights, the incentive awards program is available to recognize and encourage on-the-job initiative and achievement, whether or not the idea is patentable.

(*c*) *Licenses to the Government*

In what cases, when title is left to the employee, should the Government be entitled to a license for all governmental purposes?

Discussion under (a) and (b) has dealt with situations in which it is believed that the Government should be, and under Executive Order 10096 and the Department regulations is, entitled to an assignment of rights in employee inventions. In all other cases, when the invention is related to his work or is made with a contribution of Government resources or facilities, the Government should be entitled to a license; the employee should not be entitled to assert a right and levy a toll against the Government which as his employer has contributed to the inventive result.

This is the effect, in any case, of the statute (28 U.S.C. 1498) which permits Government employees to sue the Government for infringement of patents owned by them, but provides:

> * * * This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

In at least one case, however,[86] the Chairman of the Government Patents Board has found in the more ambiguous language of section 1 (c) and (d) of the Executive Order support for leaving the entire right to the employee, "subject to law" in situations where suit would

[86] See discussion in Comp. Gen. B–124998, Jan. 19, 1956.

be barred under 28 U.S.C. 1498. The case dealt with a Navy contract which provided for the payment of royalties on an employee invention in the development of which Government equipment had been used on a "permissive" basis. The Chairman had held the Government to be not entitled even to a license under the Executive Order and Navy regulations. The Comptroller General concluded that under the Executive Order the Government was entitled at least to a license, and that in any event 28 U.S.C. 1498 indicates that—

> it is the settled policy and intent of Congress that public funds should not be expended for the use of inventions of Government employees which are not wholly unrelated to the duties of such employees, or in the development of which Government facilities or interests are used.

Although in the Navy case the invention could also have been found to be related to the "official functions" of the employee, the decision appears to adopt the construction that either relation to such functions or the use of Government facilities or materials is sufficient to entitle the Government to royalty-free use. This is supported also by the legislative history,[87] and any lesser right clearly would lay the Government open to gross exploitation by its own employees.

The Department of Health, Education, and Welfare, when it has determined that the Government has contributed to the making of the invention but that, either because of insufficient contribution or insufficient interest, the Government will leave title to the invention in the employee, has in all cases reserved to the Government—

> a nonexclusive, irrevocable royalty-free license in the invention with power to grant licenses for all governmental purposes.

In so doing it follows the language of section 1(b) of the Executive Order with results which are in harmony, and not in conflict, with 28 U.S.C. 1498. This has obviated the need for weighing further the quantum of the Government's contribution in terms of time, material, or facilities once the determination is made that it is—

> insufficient equitably to justify a requirement of assignment to the Government of the entire right.

Conclusion

The Government should have a nonexclusive, irrevocable, royalty-free license for all governmental purposes in any invention made by a Government employee under circumstances which do not require assignment when the invention is made with a contribution of Government facilities or resources, or of the working hours of the inventor or any other Government employee, or which is related to his official duties.

2. GOVERNMENT-OWNED INVENTIONS

(a) *Patenting or publication for defensive purposes*

Is the patenting of Government-owned inventions necessary or desirable, and under what circumstances, to protect against the risk of appropriation by others?

Criteria for determining whether an invention should be dedicated to the public by publication or should be patented are spelled out in

[87] 1952 United States Code Cong. Serv., pp. 2322–2324.

the Department's manual on "General Administration." [88] In general, it specifies that patenting should not be recommended when printed publication of a technically adequate description can be or has been arranged, or when disclosure to or use by others can be or has been arranged, under safeguards which will assure the availability of proofs as to time of conception, reduction to practice, and disclosure. Patenting, however, is appropriately recommended, in the case of an invention of high potential significance to public health, safety, or welfare, to obtain maximum assurance against a potential rival claimant establishing priority by showing a date of invention (followed by diligence in reducing to practice) earlier than the Department's publication date.

Guidance is also given as to what constitutes an adequate technical disclosure and as to the making and retention of records which will constitute evidence of invention. Each operating agency within the Department is enjoined to—

> require of its research workers the making and preservation of records which will serve a probative purpose * * * only to the extent deemed consistent with good research practice * * *

It has not been possible to secure a report on the total number of employee invention reports on which it has been determined that publication will suffice to protect the public interest. A report from the National Institutes of Health indicates 22 such determinations on inventions of Institute employees alone in the period 1953–58. By contrast, in this same period seven patents were issued on employee inventions (all in the Public Health Service) for the Department as a whole. The periods are, of course, not comparable since there is a lag of at least a year (and more often 3 or 4 years) after the original determination to seek patent protection and the issuance of a patent; moreover, the proportion of cases in which patenting is sought is rapidly declining as the policy of reducing the number of patent applications is increasingly observed.

Since the patent law attaches certain defensive advantages to patenting, the Department policy of favoring publication rather than patenting undoubtedly lays the Government's interest in the inventive product of its activities open to certain risks. Granted that the risks exist, they are at least calculated, and they have to date led to no debacle. Although on one application for a patent now pending interference proceedings have developed, there appears to have been no case in which publication has been relied upon in which the invention has been appropriated by others claiming prior invention.

It is time, in any event, to raise the question whether the risks of possible adverse patenting, under a well developed publication policy, are not more than overbalanced by the risks of a different type which are inherent in a publication-fearful, patent-conscious, property-interest type of approach in Government research. The Department regulations declare that—

> * * * Except where deemed necessary for protecting the patent claim the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[88] Department Manual, General Administration—pt. 6–30—Criteria for Patenting or Publication—Proof of Invention (Issuance of Sept. 17, 1950).

The requirement of confidentiality under these regulations is confined to invention reports required from employees or others for the purpose of obtaining determinations of ownership or for the purpose of prosecuting patent applications.[89] The policy which favors prompt dissemination of information concerning the results of research means that publication or arrangements for publication usually have been made before determinations are made as to patenting. The subordination of this release of information, generally, to the delays incident to patent-dominated procedures would run counter to the sound objectives of the Department's research programs.

Legislative proposals which would require all records and reports pertaining to inventions to be kept confidential would therefore be viewed with the greatest concern by the Department.[90]

It is to be noted that the problem of protection when an invention has actually been reduced to practice differs radically from that which exists when extensive development is required. In the first situation, the problem is simply that of protecting the inventive product of Government research against adverse claims. For this, two techniques are available: adequate disclosure and publication, or patenting (itself a matter of disclosure and publication). Amendments which have been proposed to the Patent Code would provide an intermediate course. These would authorize the publication of patent applications on Government-owned inventions in lieu of further prosecution, at the discretion of the applicant and when deemed by the Commissioner to be in the public interest, the object being to provide the Government with defensive protection and to save the waste incident to full prosecution of the patent application and administration of the ensuing patents.[91]

Where the invention has not been reduced to practice a patent application serves as defense against a claim that the inventor, although first to conceive the invention, had not exercised diligence in reducing the invention to practice; it serves therefore to protect the head start of the inventor who first had the conception as against other claimants. The importance of this feature to the inventor (or his assignee) seeking exclusive control in order to exploit the invention for his own advantage is apparent. In the case of an invention of great procurement interest to the Government, preservation of the Government's priority status in the research effort may similarly be of extreme importance. In the case of research activities which, like those of the Department of Health, Education, and Welfare, are directed primarily to the advancement of knowledge and its useful application, the broadening of the research efforts is itself a goal; and for this purpose the prompt publication of significant, even though unperfected advances, is generally indicated. If proprietary rights in the invention are to be protected, it is of course imperative that the publication be technically adequate in order to start the running of the 1-year period which will foreclose the possibility of a successful patent application by any claimant. In a program like those of the Depart-

[89] 45 C.F.R. secs. 6.2 and 6.4.

[90] See section 3 of draft resolution presented by the late Benjamin Dowell, Chairman, Government Patents Board. Hearings before Subcommittee No. 3 of the Committee on the Judiciary, House of Representatives, March 3 and April 25, 1958.

[91] See pp. 7 and 13, S. Rept. 1430 (1958), report of the Committee on the Judiciary by its Subcommittee on Patents, Trademarks, and Copyrights. See also discussion, Finnegan and Pogue, "Federal Employee Invention Rights," 55 Mich. L. R. 953–956 (1957).

ment, however, occasions for a patent application to preserve for a longer period the Government's priority position in reducing the invention to practice will be comparatively rare.

At present, Executive Order 10096 and the Department regulations require employees to report all inventions which relate to their work or which involve the use of Government facilities in any way. These reports are fairly formidable, as they must be if they are to serve as a basis for determination of legal rights and interests. The fact, however, that they lie outside the normal channels of scientific reporting makes them onerous to those inventors who do not assert any proprietary right. These reports, when all needed information is included, are then reviewed and various determinations are made by a series of officials: by the head of the constituent agency in the Department (for example, by the Surgeon General of the Public Health Service) following reports and recommendations received from various subordinate officials, the Department's Patent Officer, and (generally, also) by the Chairman of the Government Patents Board. When it is considered that the Department is now recommending publication rather than patenting in almost all cases, the redundancy, waste, and delays inherent in such a procedure are dismaying.

It seems apparent that the development of publication policies throughout the Department's research establishments, which would include instructions on technical disclosures adequate for patent protection purposes, might provide an adequate basic structure for the handling of the inventive results of research. This would relieve research workers, supervisors, and patent machinery alike of a largely needless routine of individual invention reports through specialized administrative patent machinery and would free the patent machinery (whatever it may be) to deal carefully and individually with two situations: (1) cases in which the employee claims rights in the invention as against the Government; and (2) cases (as a rule limited to the more important inventions) which call for consideration of possible patenting for defensive or control purposes as one factor in the total handling of the new development. Such a setup would have the virtue of keeping emphasis on the research objective but would relate to it the criteria which, because of the patent system, sometimes call for formal determinations of rights and for policy decisions of real importance.

It is difficult to estimate the extent to which inventors now fail to send in the required invention report. In the case of workers totally absorbed in research efforts, sheer unfamiliarity with the requirement is a factor hard to overcome. There are also cases in which the less absorbed inventor seeks to patent independently, in his own interest and without any determination of rights by the Government. This is a situation which can be met only in part by regulations. The legal infirmity of the employee's right in such cases brings its own pressures; since Federal Register publication of regulations, which state the criteria for determination of the Government's rights, the Government employee seeking a patent is more and more frequently advised by his patent attorney (or the patent attorney of his prospective assignee) to obtain a determination of rights under the machinery established for that purpose. Finally, there are cases where inventions are not reported simply because they are trivial, there is no claim of

adverse interest, or the determination procedure is obviously needless because a determination as to the sufficiency of publication is a foregone conclusion. In one of the instrument laboratories of the Service where the invention policy is best understood, and potentially patentable inventions are frequently developed, the making of invention reports on minor inventions is now deliberately omitted, largely to avoid the swamping of the already overburdened patent machinery.

This experience emphasizes that, as always in Government, procedural requirements that exceed needs are self-defeating and invite evasion or neglect. At the levels at which determinations are made, too great a load will lead either to undue delays or perfunctory determinations, both dangerous to effective decision. The writer is of the view that the recommendations of the Attorney General's report to the President in 1947 and the requirements of Executive Order 10096 and the administrative orders of the Chairman of the Government Patents Board are excessive and unrealistic in this respect, and that amendment of the patent law itself to require disclosure of the inventor's relationship to Government employment may provide a simpler means of identifying the need for a determination of the respective rights of the inventor and the Government. The requirements for research programs which are oriented toward the development of secret materials and the Government's own procurement needs may differ in this, as in other respects, from those of the Department of Health, Education, and Welfare.

Conclusion

Under a publication policy geared in general to the dissemination to the public of the results of research, but administered with due regard for technical adequacy and promptness, the risk of appropriation by others of inventions which have been reduced to practice is minimal, and the dangers less than those inherent in a policy which would subordinate research programs in the public interest to patent considerations. In the case of inventions not yet reduced to practice, preservation of the Government's priority position by the filing of a patent application is more frequently indicated. The significance of the invention and the likehood of early success in the effort to reduce to practice are factors here. The requirement in every case of an invention report, and a formal determination of rights as to the method of protecting the Government's interest (by publication or patenting) is unwieldy and wasteful. It tends to clog and render less effective the administrative channels which should be kept open for prompt and careful determinations in two types of situations: (1) where there is a claim of interest adverse to the Government, and (2) where, if the invention is one to which the Government is entitled, there are factors which point to the need for patenting or other special steps to protect the Government's interest.

(*b*) *Patenting for quality content*

Is patenting necessary or desirable, and, if so, under what circumstances, in order to control the quality of the product?

The extent to which knowledge and know-how should be suppressed because it might be dangerously used is a question beyond the scope of this paper; the extent to which it should, when the power

exists, be patented in order to assure only its safe use by qualified users is not beyond its scope. It is one thing to say that a private property owner is under an obligation to use his property in a way that will not cause injury to others; it is quite another to say that the Government should reduce rights in inventions to patent form in order to regulate their manufacture and use.

The regulations of the Department provide that, except in unusual cases when it is determined that unconditional licensing would be contrary to this public interest, licenses will be issued to all applicants and will contain no limitations or standards relating to the quality of the product to be manufactured, sold, or distributed thereunder.[92] The head of the constituent agency is required to recommend whether the Department should seek to obtain a patent or whether the invention should be published or other action taken in the public interest, giving his reasons therefor.

Examination of invention reports indicates that inventors and immediate supervisors frequently recommend patenting as a method of control of the quality of the product. Disregard of his recommendation that a patent be obtained for this reason was a part of the dissatisfaction of the inventor in one of the two appeal cases in the Department. (See p. 34.) Such recommendations seldom reflect appreciation of the difficulties involved in making such control effective. The validity of the recommendation clearly depends upon whether a condition embodied in a license would be enforced against a noncomplying or unlicensed manufacturer. The possibility of a civil action theoretically exists, it is true, but to date there has been no record found of an infringement action for unlicensed use of any Government-owned patent nor of a suit to enforce a condition of quality spelled out in a license under such a patent.[93]

The Department's experience with quality control licensing is limited but illuminating.

The drug "primaquine" was invented by Dr. Robert Elderfield and Dr. Eleanor Werble, working under a Public Health Service grant at Columbia University. The drug has highly effective antimalarial properties; it is also toxic in character, and great care in its manufacture is required to prevent harmful effects. All rights were assigned to the Government, pursuant to the terms of the grant, and patenting was expedited because of a strong possibility that interference proceedings would develop. Patent issued in 1952. The invention was extensively licensed under the ensuing domestic patent (see p. 48 for the treatment of foreign rights), but in the end the only quality condition, if it could be called such, was one making the manufacture and sale subject to compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. These, of course, would have been legally applicable in any event. However, Dr. Elderfield's quality standards for the manufacture of primaquine were furnished to licensees and were available to the Food and Drug Administration to take into consideration when passing upon new drug applications.

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[92] 45 C.F.R. sec. 7.4.

[93] Attorney General's report, vol. 1, final report, p. 112. Checked orally as of Oct. 1, 1959, with Mr. Hayward Brown, Chief, Patents Section, Department of Justice.

In the exploration at that time of the problems of quality control the Public Health Service shared with the inventor a—

reluctance to be responsible in any way for making possible the production of drugs of a quality less than that which would be desirable from a health standpoint.

However, it recognized that as a Government agency it had inherent responsibilities and limitations, for example, in the selection of licensees, quite different from those of a private firm in the disposition of its own property.

It has now become clearer to us that in the absence of adequate statutory authority and appropriations which would be needed to do a competent job of patent administration we should generally confine our control of the quality of licensed products to the standards existing in our agency's established programs. This conviction is strengthened by our belief that it may be possible to achieve equal or better results in that way.[94]

In the case of the patent issued in 1959 on a process for a serologically active fraction of virulent treponema pallidum, useful in the detection of syphilis, quality control was a primary consideration in the Surgeon General's recommendation that a patent be obtained.[95] The Department of Defense, which actually handled the patent application, was also interested in the quality aspect as affecting the venereal disease programs in the armed services. Inquiry of the Food and Drug Administration within the Department indicated that the reagent would constitute a drug within the statutory definition in the Federal food and drug legislation; while, therefore, it was within the reach of its power it was not of a class of products being actively checked at that time. No requests for licenses under this patent have yet been received, and the conditions for licensing to assure quality of manufacture have not been prepared. It is not clear why reliance on legislation and regulations now on the books would not be as effective as reliance on conditions in a license; or, if existing legislation is inadequate, why language to fill the gaps should not be recommended.

Of even greater interest are the licenses under patents on morphine derivatives or other narcotics, notably, on Metopon on which a patent was obtained while the Public Health Service was still in the Department of the Treasury. In this area, there is a strong body of legislative control, both as to quantity and quality, in the Harrison Narcotics Act, and in its various amendments, as well as obligations under treaties to which the United States is a party. The licenses to manufacturers and distributors which were issued (both before and after the transfer of the patents themselves to the Federal Security Agency) followed the recommendations of the Bureau of Narcotics of the Treasury Department, which acted with the advice of the National Research Council's Committee on Drug Addiction and Narcotics.[96]

In 1951 the Committee on Drug Addiction and Narcotics found that the licenses appeared to be retarding the medical use of the drugs and recommended that they be revoked and that the patent be dedicated to the public. A group which included both representatives of the Bureau of Narcotics and the drug companies agreed unanimously that

[94] Letter to Dr. Elderfield, from Mr. Ernest Allen, Chief, Division of Research Grants, National Institutes of Health, Jan. 9, 1952.
[95] Determination of Surgeon General of Aug. 24, 1955, regarding invention of Dr. Portnoy.
[96] Letter of Feb. 6, 1951, to Mr. Oscar Ewing, Administrator, Federal Security Agency, from Dr. Nathan Eddy, standing committee, drug addiction and narcotics.

"there seems to be no present need for continuing restrictions on Metopon other than those imposed by the Federal narcotics laws and regulations." After consultation with the Justice Department, it was determined in this case to make the patent available for unrestricted licensing rather than to dedicate the patent itself to the public.

The recent discovery at the National Institutes of Health of the synthetic drug (phenazocine) having pain-reducing qualities similar to certain opiates but without similar habit-forming effects has again demonstrated the inappropriateness of Government licensing under a patent as a substitute for regulatory control. In the case of the new drug, the Bureau of Narcotics again recommended restricted licensing under a patent to be obtained by the Government; the Secretary of Health, Education, and Welfare, in acceding to the recommendations, relied upon the Bureau's special responsibilities in this field as a basis for a finding (as required under the Department's patent regulations) that unrestricted licensing would be contrary to the public interest. It was recognized, however, that control of this and similar narcotics should not rest upon the circumstances of Government ownership of a patent right, but should extend with criteria appropriate to the exercise of Government regulatory control, to all such drugs regardless of ownership.[97] The "Narcotic Manufacturing Act of 1960" (H.R. 529), which passed the House in the 1st session of the 86th Congress, would provide—

> a system of licenses and manufacturing quotas for all manufacturers, with appropriate safeguards, with respect to the manufacture of the basic classes of narcotic drugs, both natural and synthetic, for medical and scientific purposes.[98]

This is an intricate piece of legislation and indicates very well the delicacy of the regulation problems involved.

Conclusion

Control of the quality and quantity of products and tests of the competence and responsibility of manufacturers, to the extent of demonstrated need therefor, is properly exercised by Government under legislation of general application specifying the responsible agency and the nature and extent of the control to be exercised. This is particularly necessary to assure proper administrative safeguards when, as in the case of narcotics control, quantity limitations and selective qualification of manufacturers are required. Except on a purely interim basis, pending the recommendation and enactment of appropriate legislation, there is no place for controls based on a chance proprietary interest of the Government in a patent on a particular invention.

(*c*) *Foreign rights*

Is it necessary or desirable to leave to employees, grantees, or contractors the foreign rights on inventions to which the Government acquires the domestic rights?

The place of governmental control over patent rights as a matter of foreign policy, whether nationalistic or cooperative, is outside the scope of this study. It is clear, however, that notwithstanding in-

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[97] Memorandum of Mar. 9, 1959, from Surgeon General Burney to Secretary Flemming, HEW, "Determination by the Secretary of Conditions for Licensing of Narcotic NIH 7519 and Related Compounds," dated Apr. 8, 1959.

[98] H. Rept. 1053, 86th Cong.

creased provision for safeguarding information in certain limited areas, the present trend is toward freer and fuller sharing of information, techniques, and know-how. Changes which have occurred in this respect since World War II, and therefore since the report on patent policies made to the President by the Attorney General in 1947, mark a more active interest in the availability to others than the American public of the results of research.

The trend is strongest with respect to knowledge and inventions significant for general human welfare, particularly in the health field. As in the domestic field, the Department of Health, Education, and Welfare, more than other agencies of the Government, may be expected to support, and be charged with responsibilities for the dissemination and sharing of the results of research. A striking instance of this trend is the international medical research bill. This measure, which has already passed the Senate (S.J. Res. 41, 86th Cong.),[99] is designed to provide for an assault on disease through international cooperation in research, research training, and research planning. The hearings in the Senate and the House demonstrated wide support for the bill as a means of forwarding the goal described by the President as "a great shared effort toward the triumph of health." The rapid interchange of knowledge and information is declared to be one of the basic purposes of this resolution.

Department experience with foreign patent rights is limited but significant. It is necessary to set it against the framework of the control, supposedly exercised but virtually inoperative, under Executive Order 9865 of June 14, 1947, establishing a foreign patent protection program. This order, which antedated Executive Order 10096, required all agencies of the Government wherever practicable to acquire foreign rights in inventions resulting from research financed by the Government. It also provided administrative machinery for the prosecution of foreign patent rights and their administration. This program, designed to establish a portfolio of Government-owned foreign patents to be used for trading purposes and to promote foreign commerce, failed to elicit support from industry or appropriations from Congress. Administrative responsibilities were shifted from the Department of Commerce to the Chairman of the Government Patents Board and by delegation back to Commerce and the respective agencies. In connection with the shift of responsibilities in large part to the respective agencies, the Department of Health, Education, and Welfare had expressed the view that it had no funds and no general authority to administer foreign patent controls.

A working committee of the Government Patents Board in 1955 agreed that the Executive Order had not served its purpose. Whereas the majority would have rescinded the Order, leaving the several agencies to their own devices, the minority report (which represented the views of the State Department) favored amendments which would generally provide for acquisition of foreign rights to inventions with respect to which the Government was entitled to the domestic rights and would utilize disclosure by publication as the primary means of

[99] S.J. Res. 41, 86th Cong., became Public Law 86–610 on July 12, 1960, after this paragraph was written. See hearings, International Health and Medical Research Act of 1959, Senate Committee on Labor and Public Welfare, February 1959; International Health, House Committee on Interstate and Foreign Commerce (subcommittee), August 1959. For an earlier report on organization and financing of, and participation of the United States in, international health programs, see H. Rept. 474, 85th Cong., 1st sess.

preserving the rights to use of such inventions abroad.[100] On these issues the Department of Health, Education, and Welfare concurred with the minority report.

What now remains is a rigmarole, unresolved by Executive action, which leaves the agencies subject to an Executive Order no longer operative according to its terms, and to administrative orders 6 and 7 of the Chairman of the Government Patents Board issued in 1954, the operation of which have, however, been "suspended" in part, without formal amendment.[101] At the time of writing the situation seems to be as follows: The responsible agency, when the Government is entitled to acquire foreign rights in an invention made by an employee or contractor, is still nominally required to obtain an option to acquire such rights, but may simultaneously with the acquisition of the option elect to forego it. With the approval of the Chairman of the Government Patents Board the agency concerned may disclose by publication instead of patenting; if the Government does not act, its failure represents a determination to leave rights to the inventor.

In those circumstances in which the Government is entitled to rights in employee inventions, no reason is seen for distinguishing between the domestic and foreign rights; the justifying circumstances, i.e., those attending the making of the invention, are the same. Executive Order 10096 itself appears to contemplate no distinction. Section 1 provides for acquisition of the "entire right, title, and interest." Exception is provided in those cases where the contribution of the Government is insufficient equitably to justify assignment to the Government of the entire rights; in such cases title is left to the employee subject to a license for all governmental purposes "such reservation to appear, where practicable, in any patent, domestic or foreign."

The practice of distinguishing between domestic and foreign rights had, however, been followed by several agencies before the issuance of the order, and notably by the Department of Agriculture. It is, moreover, in accord with the recommendations of the 1947 report of the Attorney General which, however, gave scant attention to the problem of foreign rights.[102] The general premise appeared to be that, since Federal agencies as a rule have neither the means nor a mandate for foreign patenting of rights in inventions to which the Government might acquire title it is better to leave the foreign rights to the employee who might arrange for patent protection abroad and preserve a license to the Government. Notwithstanding misgivings as to the basic premise, the Department of Health, Education, and Welfare

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[100] Report of Interagency Working Committee to Chairman, Government Patents Board, Oct. 30, 1955.

[101] Administrative orders 6 and 7, revised by the Chairman, Government Patents Board, Federal Register of June 29, 1954. The present Chairman of the Board, under date of Sept. 22, 1959, advised the writer as follows:

"The requirement to submit foreign patent protection reporting form TS–12 to the Department of Commerce, pursuant to sec. 3015(b) of administrative order 6, has been suspended.

"Therefore, secs. 301.5(b), 301.6, and 301.9 of administrative order 6 and secs. 302.5 and 302.6 of administrative order 7 are temporarily inoperative."

For a statement on the background and requirements of administrative orders at the time of their issuance in 1954, see administrative orders Nos. 6 and 7, and explanatory document issued by the then Chairman on June 24 of that year.

[102] Attorney General's report, vol. 1 final report, p. 136. The successive chairman of the Government Patents Board have also apparently not questioned the authority of agencies to leave the foreign rights to the inventor even in those cases where the United States is entitled to the full rights under common law doctrine.

has conformed to the established pattern and has drawn distinctions in its treatment of foreign rights.

The foreign patent rights left to the employee inventor of certain antibiotic inventions have already been mentioned. As there noted, the sale of rights by an employee of the Food and Drug Administration led to adverse reaction from business against the preferred position of the transferees in the exploitation abroad of Government-financed research and against compromise of the employee's disinterestness as an enforcement officer. (See p. 27.)

In the case of DDVP, foreign rights were left to the inventors without, so far as is known, any such adverse reaction and to the satisfaction of the inventors. It is the view of these inventors that financial reward for control of foreign rights is an encouragement for the recruitment of Government employees, and provides private industrial concerns a means of extending their activities abroad. These are natural reactions. The leaving of foreign rights to the inventor is not, however, any more than the leaving of domestic rights, a logical or effective means of providing for employee incentives and rewards. Moreover, the leaving of foreign rights to employee inventors may result in uses at variance with public policies of the United States in the international field, such as agreements relating to the reciprocal use of inventions, the prevention of export monopolies, and encouragement of the broad use of Government inventions by industry.[103] To the extent that the United States has policies which involve the foreign use or patenting of inventions to which it is entitled, it should not be in the position of relying on its employees to do for it an agent's work without an agent's responsibilities.

The antimalarial drug "primaquine" has been mentioned (p. 46). Developed by a grantee of the Public Health Service, all rights in the invention were assigned to the United States under the terms of the grant. The foreign rights in this drug were the subject of keen commercial interest. This was one of the comparatively small number of inventions to which Executive Order 9865 was applied according to its terms. The Department of Commerce undertook the active administration of the foreign rights but was without funds to finance patenting abroad. In the case of certain other antimalarial drugs, a group of commercial companies had financed the securing of patents abroad. In the case of primaquine, however, the inventor, Dr. Elderfield, felt strongly that while patenting was desirable as a means of protecting the quality of the manufacture, exclusive foreign licensing would be discriminatory against firms which had been most cooperative in their research efforts and might be severely criticized.

Solution was reached under agreements made by the Commerce Department with the Burroughs-Wellcome Co., whereby that company bore the cost of the foreign patent protection under a license which was not exclusive and contained no provision of special advantage to the company except the Government's agreement to advise the company of applications for licenses received from foreign firms. As of July 1955, 25 foreign patents for this and certain other antimalarial drugs were the only ones still in force under the foreign patent pro-

[103] Report of Interagency Working Committee, supra, note 100.

tection program of the Department of Commerce, Office of Technical Services, and the financing companies had notified that Office that many of these were to be abandoned.

The latest effort of the Department to handle foreign rights to protect the public interest through patenting relates to "phenazocine," the narcotic drug on which domestic patent application is now pending.[104] In accordance with administrative orders by the Chairman of the Government Patent Board under Executive Order 9865, an option to take the foreign rights was first reserved and was subsequently exercised. Highly aware of the international significance of this drug, and of the absence of any provision in the Department or elsewhere in the Government for the administration of the foreign rights, the Department turned to the World Health Organization and formally proposed that it should acquire the foreign rights and administer the resulting patents. The object was to insure the utmost availability of the new drug for the general health and welfare of the peoples of the world, subject to the provisions of relevant treaties controlling the production and distribution of narcotic drugs.

This was the first time a member government had proposed to place the administration of rights in a pharmaceutical preparation on an international basis. The similarity of objectives between the Department and the WHO was in this case complete, and the Director-General, Dr. Candau, expressed the liveliest appreciation and interest. Within the time available the proposal was accorded the most careful consideration by WHO—

> in the light of the constitutional functions of the World Health Organization and its legal status, the technical aspects of the matter, and the laws governing the protection of industrial property.

In the end the offer was declined.[105] The reasons which led WHO to this decision parallel to a striking degree considerations which have shaped the thinking of the Department on patent matters. They may be summarized, very roughly, as follows:

1. The administration of patent rights, and their defense against third parties, would involve the organization in a quasi-commercial field in which it has no specialized knowledge or experience, and may be outside the legal competence of the organization.

2. Impartiality, as a requisite of WHO in the field of narcotic drugs, might be prejudiced by its administration of rights in a particular drug, especially one which might or might not be the most desirable from the health standpoint, and by necessary determinations as to which country should be permitted to manufacture the drug.

3. The patent laws of many countries present formidable difficulties on the securing and maintenance of patents, particularly on medicaments, and the alternative of publication would furnish reasonably adequate protection against exclusive appropriation by others.

On the last point, the Director General transmitted a "Study of the Means of Preventing the Acquisition of Exclusive Rights With Re-

[104] Serial Nos. 771,165 and 771,166.
[105] Letter from Dr. M. G. Candau, Apr. 10, 1959, to Dr. L. E. Burney, Surgeon General, Public Health Service.

spect to NIH 7519" which was prepared by the United International Bureau for the Protection of Industrial, Literary, and Artistic Properties and which includes an analysis of the laws of the principal countries.

The Director General of WHO concluded his consideration of the proposal by an offer to make available all existing facilities and services, including technical publications, of WHO with a view to disseminating information on the drug to member States. The Secretary of Health, Education, and Welfare, in October 1959, in turn approved the recommendation made to him by the Surgeon General, that protection of the invention abroad, with a view to its widest availability within the limits of international conventions for the control of narcotics, should be sought through a program of disclosure and publication. This program would utilize normal scientific channels and the publication facilities of WHO and of the State Department operating through its representatives and media in foreign countries.

This incident, together with prior history in the Department, indicates that, except for inventions which are to be exploited for commercial or proprietary purposes, the protection in foreign countries of Government-owned inventions, especially drugs, is best sought through the development of techniques of publication rather than patenting. Further, it suggests that the leaving of rights in inventions to which the United States is equitably entitled, either to the inventor or to a contractor, for private exploitation lays the Government open to charges of discriminatory preference, or of a lack of regard for the general public interest in the results of research.

Conclusion

Generally, the circumstances which equitably entitle the Government to the domestic rights in an invention entitle it to the foreign rights as well. Under a cooperative international approach the considerations which apply to the availability of the results of Government-financed research in this country, particularly the availability of inventions relating to health and welfare, apply generally to their availability abroad. Generally, as in the domestic field, a vigilant policy of publication will suffice to protect the Government-owned invention against claims of prior invention by others.

When as an incident to foreign policy or to provide additional protection against adverse claims, it is determined that patenting, and the maintenance of patents in foreign countries, is desirable in the public interest, the Government should act through a public agency, equipped by specialized experience and financed with adequate appropriations for this purpose. The granting of exclusive rights in inventions to which the United States is equitably entitled, either to the employee inventor or to a contractor for private exploitation, lays the Government open to charges of discriminatory preference, or of a lack of regard for the public interest in the results of Government-financed research, and, in areas where the agency has regulatory responsibilities, may compromise the impartiality of its administration.

The lingering controls supposedly, but not actually, exercised under Executive Order 9865, are unrealistic, stale, and unprofitable. In the absence of centralized patent machinery, with operating powers, appropriate consultations with the Department of State and the Department

of Commerce as to foreign policy and international commerce aspects are all that is required to supplement procedures available to the responsible agency for the handling of foreign as distinguished from the domestic rights.

(*d*) *Licensing*

Is power to issue limited or exclusive licenses necessary or desirable, and under what circumstances, in order to foster or assure the development of a patentable invention arising from Government-financed research?

The basic question here is one to which the Department has attempted no answer. In the case of employee inventions, invented under circumstances which entitle the Government to ownership of the invention, exclusive licensing is generally viewed as beyond its power, under present law, since this would amount to a disposition of Government property without congressional authorization.[106] The same objection would apply also to exclusive licensing of Government-owned foreign rights. Some of the experience gained with respect to foreign rights where these have been "left" to the inventor, illustrate problems which would attend selective licensing of domestic rights as well.

There has developed, so far as the writer has discovered on the basis of limited inquiry, no persuasive body of evidence that employee inventions or others to which the Government has acquired the full or domestic rights, have failed of development because of the Department's inability to license exclusively. This is an area in which information is not readily obtained. Followup on the commercial development of inventions made available to the public, either through publication or patenting, is a matter which lies outside the statutory responsibilities of the Department, and even at best, what would have happened had the administration of inventions been other than they actually were must be largely conjectural.

In the field of grants, however, departmental policy statements explicitly recognized that—

> in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available.[107]

The Department has, for this and other reasons, laid on the heads of the operating agencies within the Department the responsibility for exercising judgments on a factual basis. This sometimes involves the question of whether exclusive licensing in a given case should be permitted, and on what terms. The experience of the Division of Research Grants, Public Health Service, has been in this respect the most extensive within the Department and has therefore been examined as a part of this study.

Under the Department regulations occasions for exercising judgments with respect to invention development and utilization, may arise chiefly in two situations: (1) when the Surgeon General is asked to accept the institution's own established patent policies (with or

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[106] Constitution art. 4, sec. 3, ch. 2. Congress has power "to dispose of * * * property belonging to the United States." Granting of a nontransferable, nonexclusive, irrevocable license under a Government-owned patent is not a disposal of the monopoly, and not a disposition of property. Opinion of Attorney General Stone, 34 Op. Atty. Gen. 320 (1924).

[107] 45 C.F.R. 8.0(c).

without modification) as a basis for leaving to the institution the function of decision as to the disposition of all inventions arising from Public Health Service grants; and (2) when, in the absence of such a standing agreement with the grantee institution, he exercises the right (reserved to him under the terms of the grant) of determination in the individual case. The grantees of the Public Health Service, as a class, are nonprofit institutions, chiefly universities.[108] As noncommercial institutions their problems in the patent field are similar in many respects to those of a Government agency, except that they are not complicated by regulatory and policing functions. Increasingly, with the growth of research and especially of research sponsored by outside interests (both profit and nonprofit) these institutions have been forced to develop their own patent policies. These vary all the way from a complete hands-off attitude to the maintenance or employment of specialized machinery for patent administration for the purpose of developing the invention and sometimes for realizing financial return to support further research and to compensate inventors. As to rights in inventions arising from sponsored research the policies generally provide that these shall be handled in accordance with the agreements with the sponsor.[109] Some are so sensitive to the issues of freedom of publication and use of the results of research that the patent clauses in Public Health Service grants have appeared to them to be too restrictive.[110]

As of November 1, 1959, the Surgeon General had entered into agreements with 19 nonprofit institutions. See appendixes G and H for list and for a sample letter of agreement. Of these 19, the policies of 18 of the institutions admit of exclusive licensing in some situations, usually tightly circumscribed.[111] The Surgeon General may approve an agreement with an institution only if he finds that under its policies—

these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties.

If the institution's policies admit of exclusive licensing the Surgeon General requires assurance that such licensing would be the exception and for a limited period only and requires—

full information on the basis on which such licenses are issued and the safeguards utilized to protect the public interest.

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[108] The general authority for grants under the Public Health Service Act (42 U.S.C. 241(c)) does not expressly exclude profitmaking institutions. To the extent that the Public Health Service has widened the class of grantees to include other than true nonprofit organizations, some of the assumptions underlying the patent policy as applied to grants may require reconsideration.

[109] See generally "University Patent Policies, a Factual Survey," directed by Archie M. Palmer, National Research Council. Also Palmer, Archie, "Patents and Nonprofit Research (Study No. 6, Senate Subcommittee on Patents, Trademarks, and Copyrights).

[110] This has been a problem in connection with applications from some foreign universities as well. An application from the University of Manchester for a grant for a research project in the cancer field was withdrawn Apr. 17, 1959, because of the required inclusion in the grant conditions of the standard patent clause. The same clause was objected to in the case of a fellowship application at the University of Leyden but, after further explanation of Public Health Service policy, the board of directors of the university were "convinced that the purpose of the Public Health Service is essentially the same as our own: to insure the freedom of publication and of the use of inventions." Letter to Miss Katherine Parent, National Institutes of Health, May 24, 1958.

[111] Harvard University policy provides that no member of the university may take out a patent concerned with therapeutics or public health, except with the consent of the president and fellows, nor will such patents be taken out by the university except for dedication to the public.

Institutions having such agreements are required to report any invention, on which a patent application is filed, in an annual report showing the disposition of the inventions. From the 19 institutions having patent policy agreements with the Public Health Service, 7 have reported to date 23 inventions on which patent applications have been filed, 12 of these being from 1 institution (University of California).

The Division of Research Grants in the National Institutes of Health receives individual invention reports from both employees of the Institutes and from their grantees, the two together constituting over 90 percent of the invention reports in the Department as a whole. See appendix F. The total number received by this Division in a 7-year period (January 1953–July 1959) was 103, of which 54 were for inventions arising from grants. Of these, 27 received during the period July 1, 1956, and July 1959 were examined to obtain a cross section (1) of the views expressed by the inventors and by the grantee institutions on the subject of patenting and (2) of the disposition made by the Surgeon General under the terms of the grant.

In cases where the institutional policy was fairly open the inventors generally expressed no personal interest in patenting except as it might serve to protect the public interest. Thus, one report (from New York University Postgraduate Medical School), relating to an invention arising from research to which several organizations had contributed, stated that none of the contributing organizations was interested in patent rights and the inventor had "no desire to patent unless this would safeguard the interests of the Government and the general public." As in the case of employee invention reports the invention reports from these institutions sometimes urged patenting on public interest grounds giving a variety of reasons. Five (at Medical College of Virginia, Washington University, University of Florida, Rollins College, Clark University) favored patenting for protective purposes; one (at Hahnemann Medical College) thought publication sufficient for protection but that royalties from a patent could finance further research; one (at University of Cincinnati) would patent for the purpose of assignment to a suitable company for development, under safeguards and without demanding royalty; three (at the University of Maryland, Stanford University, and at Eastman Dental Dispensary) in view of a limited market thought patents might be needed to assure economic development. In one case (at Wayne State University) the inventors wished to file a patent application and receive royalties, and believed a 5-year exclusive-use basis was necessary for adequate development; they would, however, be satisfied without patent arrangements. One (at Meharry Medical) would patent to protect the public interest and as a recognition of the inventor and others who had contributed to the work.

In six cases the grantee institution proposed to handle patent applications through its own machinery created for patent administration purposes (Western Reserve University, University of California, RIAS, Stanford, and two at the University of Wisconsin); of these Western Reserve and RIAS have policies of nonexclusive licensing only. In the case of Western Reserve, university policy prohibits the patenting for profit of any invention in the health field; if deemed advisable by the board of trustees, a patent may be sought but only

for the purpose of preventing exploitation by others and to protect the public. In three cases (at the Marine Biological Laboratory, Pittsburgh, and the University of Tennessee) the inventors proposed that the invention be left to the institution for handling under a contract with Research Corp.

On the 27 inventions, two reports were so delayed as to preclude determination before the lapse of the 12-month period following disclosure and publication; one invention was found to have arisen outside the scope of the grant-assisted research; and in one case determination was left, under section 8.2(c) of the regulations, to the Navy Department as the principal contributor to the research. In 12 cases the determination was of the "standard type" consisting of the following elements with slight variations:

(1) That equitable ownership is in the United States;

(2) That the best interest of the public will be served by appropriate publication (identifying the publication);

(3) That no domestic or foreign patent applications need be filed;

(4) In the event that the inventor, with the approval of the grantee institution, elects to file a patent application, such application shall be subject to a formal recordation of assignment to the United States.

In three cases the invention was left to the grantee institution; in one case (Pittsburgh) for handling through Research Corp., and in another (Stanford) on conditions harmonious with the university's own policy which assures availability through nonexclusive licensing. In one case only, involving a narcotic drug developed at the University of California, was an exclusive license specifically approved on the ground of the need for development to establish its usefulness. The period approved was up to 4 years from the date of first public sale or 7 years from the filing of the patent application.

Of the cases on which determination is pending, two proposals for exclusive licenses are under serious consideration. If approved it will mean that, with three previous proposals, the green light will have been given in five cases for exclusive licensing for a limited period under patents to be sought on inventions financed in whole or in part with Public Health Service grants. In one of these earlier cases (at Johns Hopkins) the probable very long and costly period of development had been the reason for the approval of a long exclusive license; on another invention of a synthetic antigen for cancer detection (University of California), development is continuing but without striking results to date; in the case of the narcotic invention at the same university, time has been too short for any result to be expected.

In addition to the above, the Service received a report of a rumored assignment of an unreported invention. The report came from another grantee institution, one having a strict no-profit policy, which had tried to obtain information on the invention, had been informed that the information requested was not available, and been referred to a manufacturing company as the reported assignee of the patent rights. The inquiring institution complained of this as an improper withholding of the results of publicly financed research. Inquiry by the Service disclosed that there had indeed been a failure to report the invention but that no patent had actually been obtained.

The record thus summarized is not impressive as to showing need for exclusive licensing. Neither is the record at all definitive, although the reviews given by the Service to proposals for such licensing have been very painstaking and thorough, and have involved consultation with specialist panels drawn from fields in which the respective inventions were developed. Many of the grantee institutions have been concerned with the problem of assuring the development of inventions to the point of highest usefulness but, nevertheless, especially in the health field, either prohibit or restrict the grant of exclusive licensing.

Recognizing the special competence needed for patent administration many of them have turned to Research Corporation. This is a nonprofit patent foundation which distributes its total net income as grants-in-aid of research to college, universities, and scientific institutions. It has as a primary purpose the development of inventions of significance so as to render them available and effective in the useful arts. Research Corporation in 1957 had management agreements with 97 educational institutions and 1 nonprofit organization, including 10 of the 19 institutions with which the Public Health Service has agreements leaving to the grantee the disposition of inventions arising from any of its grants.

The experience of Research Corporation in the granting of licenses and fixing of royalties is, therefore, pertinent to this study. Following is a statement furnished to the Public Health Service as a basis for its review of institution proposals for handling inventions in the individual case or on the basis of advance general agreements:

> Research Corporation's licensing practices and royalty rates are difficult to categorize. The object is to encourage the development and introduction of a new product to the market by offering an attractive license to a potential licensee and at the same time obtain terms that will adequately protect the interests of the universities, the inventors, and our own grants program. No fixed royalty rate could possibly be determined which would cover every situation which might arise; however, the rate is always consonant with normal trade practice. It is the policy of Research Corporation never to issue an exclusive license for the full life of a patent. Exclusive licenses are issued occasionally, but only for 2 or 3 years and the maximum in the past has been for 4 years. An exclusive license for a few years may be issued in a case where a potential manufacturer will have to spend a great deal of money in developing and introducing a new product. The short period of exclusivity is designed to afford the manufacturer an opportunity of recapturing some of his initial capital outlay before competitors enter the field. We have found this policy has encouraged the early development of inventions which otherwise might have lain dormant. Another case where an exclusive feature is attractive is where the market for a product is known to be so small that a manufacturer would not otherwise introduce the product.
>
> In addition to the short term of exclusivity, the other safeguard utilized is the minimum royalty provision. Whenever an exclusive license is granted, a minimum royalty is written into the contract which makes it incumbent upon the licensee to develop the product in the shortest period of time and also deters a manufacturer from taking a license unless he actually intends to use it.
>
> We have found that an exclusive license used in the above fashion not only protects but promotes the public interest.[112]

The policy of Research Corporation is indicative of a very substantial experience to the effect that, even where some monetary return is an objective, exclusive licensing is rarely necessary for patent development and that, in any case, a short period of exclusiveness is adequate.

[112] Confirmed as representing current policy and practice by letter to the writer dated Oct. 2, 1959, from Mr. S. Blake Yates, vice president, Research Corporation.

The maximum in actual practice has been 4 years, and the period has now been reduced to 2 or 3.

In the light of such experience those who are reexamining the patent system as a whole, under the conditions of today, may be prompted to consider whether, for any purpose other than economic warfare and the tightening of monopolistic power positions, the 17-year life of a patent is not in any event too long. As to inventions arising from federally financed grants or contracts, to the extent that these admit of exclusive licensing at all, on the ground that it is needed in order to develop the invention, it suggests that a 5-year maximum limitation on the period of exclusivity would strengthen the policy objectives. Amendment of the HEW regulations, and the statement of "PHS invention and patent policy" to substitute for the phrase "for a limited period only" the phrase "for a limited period, in no case to exceed 5 years," would clarify and strengthen the research arms of the Department in dealing with the occasional importunate demands from grantees overly swayed by possibilities of profitable exploitation.

It does not follow that the Department should have the power to license exclusively the Government-owned inventions which it administers. Several factors enter here. First, there has been no convincing body of experience to date as to the need of any exclusive licensing to promote development and utilization; the Department's position on this has been largely one of watch and see. Second, if Government-owned inventions were exclusively licensed it would involve the Department in the selection of licensees on a preferential basis, raising many questions of conformity with general Government policy and compromising its own impartiality as a regulatory agency. Third, the administration of exclusive licenses involves a host of responsibilities, such as defense of the patent right itself, through suit for infringement or otherwise, collection of royalties, enforcement of the terms of the license agreement, all of which are foreign to the experience and competence of the Department.

If legislation were to be enacted to authorize exclusive licensing of Government inventions, it is believed that it should be accompanied by the establishment of a patent administration with specialized competence in that field subject to statutory safeguards which would assure the consistency of its operations with general public policies, such as those dealing with monopoly and restraints of trade, and those resting on the functions of particular departments such as those of the Department of Health, Education, and Welfare with its emphasis upon the dissemination of the results of research. It should be said, and it seems strange that it should need to be said, that the administration should be a public agency, and that the reliance upon employee inventors or contractors as pseudo-agents to carry out governmental policies with respect to inventions of which the Government is the owner, is both unworthy and dangerous.

In Great Britain, the National Research Development Corporation has been established for the purpose of "securing, where the public interest so requires, the development or exploitation of inventions resulting from public research." It is mentioned here only because its policy statements on exclusive licensing in general condemn such licenses as tending to monopoly but also permit them under special

circumstances when substantial capital is needed to make an invention marketable. By statute in Great Britain, however, exclusivity in respect to inventions relating to food, medicines, and surgical or curative devices is prohibited.[113]

A history of bills in Congress providing for the licensing of Government-owned patents is included in study No. 12 of the Subcommittee on Patents, Trademarks and Copyrights of the Committee on the Judiciary (pp. 35–38).

Conclusion

Limited experience with Government-owned inventions administered by the Department does not indicate that inventions have failed of development because of absence of authority to license exclusively.

In the administration of the grant program the Public Health Service has passed upon proposals for exclusive licensing, either as permitted under proposed general agreements with grantee institutions or in the case of individual inventors. The cases in which it has been found that exclusive licensing will make the invention more adequately and quickly available for widest use are few in number, and the results inconclusive.

Experience with Research Corporation, a nonprofit patent management corporation with which many grantee institutions have contractual arrangements, indicates that exclusive licensing is rarely necessary and should be limited to two or three, or at most four years.

Further experience under the grant policy of the Department should produce further illuminating data on this point.

In the case of Government-owned inventions authority to license exclusively would entail selection of licensees on a preferential basis and responsibilities not within the general scope and competence of the Department. No recommendation is made for the granting of such authority. Authorizing legislation, if such is considered, should provide for a central patent administration agency which would operate subject to general Government policies (as, for example, those against monopolies and restraints of trade) and the particular objectives of programs giving rise to the invention (for example, in the case of Health, Education, and Welfare, the dissemination of information and availability of the results of research for the general public benefit).

C. The Nature of the Administrative Problem

What is the nature of the administrative problem in the Department with respect to inventions and patents?

The Department's research programs, both those directly conducted and those involving relationships with public and private nonprofit organizations and industry, directed as they are to the public benefit and particularly to public health, inevitably raise questions of policy which are distinct from those of agencies whose interest in research results is largely for purposes of procurement for Government use.

The Department Patents Board has served the Department well in

[113] "Development of Inventions Act," 11 and 12 Geo. 6, ch. 60. See "An Introduction to the National Research Development Corporation," booklet published by the corporation, 1 Tilney Street, London W 1.

furnishing a continuous and informed advisory body to the Secretary for the establishment and adaptation of policy standards. The need for such a body will continue, as more of the operating agencies within the Department are charged with research programs and authority, and as contract authority is broadened. Because of the involvement of employees' interests, the Board should include always an officer familiar with personnel problems, as well as persons representative of the research programs of the Department and one or more who are familiar with overall Department objectives.

Responsibility for carrying out Department policy has been decentralized to an unusual degree. The effectiveness of policy, therefore, depends largely on administrative coordination within the Department. In this the Department has been weak. A patent officer is provided for in the Department manual to act as secretary to the Board and as a coordinator of procedures within the Department, and attorneys in the Office of the General Counsel have been successively named to this post. In no case, however, has the patent officer been sufficiently free of other duties to give it adequate attention. The constituent agencies of the Department in turn have been slow in setting up central control points within their own organizations, and where, as in the Division of Research Grants in the Public Health Service, employees have been named to handle the rapidly increasing flow of invention reports, they have been handicapped by insufficiency of staff and lack of means to secure effective coordination within the research branches of the Service. As of the time of writing, however, there are indications that the Service is moving to correct these defects.

It is interesting that a recent analysis by Captain Robillard, Assistant Chief of Naval Research, concludes that the Department of Defense with its vast and very different research programs, suffers also from weakness in the coordination of patent matters.[114] Captain Robillard's analysis shows that, although the legal functions which are performed are unique and constitute a recognized specialty in the field of law, most of the functions performed with respect to patents are now in the nonlegal fields.

In the Department of Health, Education, and Welfare, with its policy of dedication to the public of the results of research and its deemphasis on patenting as such, the problem is much more educational and administrative. Moreover, if the administrative tasks were vigorously resurveyed and procedures established, with a basis of proper records and workflow, it should be possible both to reduce, and to speed up, the load of case-by-case considerations, which are repetitive and often unnecessary. The great need is for (1) education on the fundamentals of policy and procedure, including appeals procedure, among the research arms of the Department and cooperating research institutions, (2) closer followup of reporting requirements and policy controls, and (3) prompt top-level consideration of major policy developments, especially with respect to industrial contracts, with attending consideration of possible legislative needs.

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[114] "Government Patent Administration, Policy and Organization," by Capt. George N. Robillard, USN, Assistant Chief of Naval Research, in Patent, Trademark and Copyright Journal, vol. 1, p. 270, December 1957.

The Department, in its development of a patent policy, has been happily free of the dominance of patent attorneys whose specialty and interest must lie primarily in the exercise of the patenting technique. It is, of course, essential that the advice of the Office of General Counsel be available on all legal aspects of policy and procedure. Experience in patent law is a desirable, but not essential, qualification for this purpose. The number of inventions which the Department seeks to patent, under existing policy, is too small to justify the employment of a patent attorney for the technical work of searches and patent applications. So long as this is so it may be preferable to contract for the services of patent attorneys who are specialists in the particular field of the invention, or to secure such services on a reimbursement arrangement from other agencies having specialized patent staffs.

The procedures now required under Executive Orders 10096 and 9865 contribute to unproductive delays and duplications in the administrative process. Witness the continuance of special provisions on foreign rights (see p. 48), the foundation for which has long since been abandoned. Witness also the review (apparently pro forma) of every case of the Department's reliance on publication instead of patenting as sufficient to protect the public interest; the review in every case of a determination that the Government is entitled to a license, on the basis of Government contribution or relation to the employee's duties, to determine not merely whether the Government has taken too little, but whether (even in the absence of any employee appeal) it has taken too much. This excess of review in individual cases is unaccompanied by the publication of precedent decisions involving basic interpretations of the order.[115] Is it to be regarded as meaning what it says and, especially in the light of its promulgation, as a declaration of executive policy to fill in the void in policy which the Supreme Court found to exist in the *Dubilier* case? Or is it to be regarded merely as the setting up of rules and machinery for the application of the criteria which *Dubilier* found to be controlling in the absence of executive or legislative policy? The trend of decisions is to be gleaned from the satisfaction of agencies which originally opposed the order and from statements of the chairman criticizing the language of the order and indicating that it is not being literally interpreted.[116]

Clarification of basic governmental policy, and elimination of unnecessary administrative superstructure, is essential to an understandable and effective operation.

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[115] Failure to publish decisions is attributed to agency objections and to the executive nature of disclosures regarding patentable inventions. This would, of course, not preclude the publication of basic interpretations.

[116] See, for example, statement of Lt. Col. Willard J. Hodges, Judge Advocate General's Corps, Department of the Army, at p. 14, hearings before Subcommittee No. 3 of the Committee on the Judiciary of the House, Mar. 3 and 25, 1958, and statement of Mr. Benjamin B. Dowell, Chairman, Government Patents Board, ibid., at pp. 25–26. For an example of an agency position minimizing the Government's claim to title under the order, see "Patents and the Air Force Employee," a pamphlet issued by the Air Research and Development Command (1959). Capt. R. A. Fitch of ONR, at a recent meeting of the Committee of the Federal Council on Science and Technology, characterized the order as written as "bad" but added that "However, by liberal interpretation the military services have attempted to follow the rule in the *Dubilier* case and permitted employees to retain title to their inventions subject to a royalty-free license to the Government."

Also see Finnegan and Pogue, op. cit. supra, note 60, stating that in the opinion of the authors, based on analysis and interviews, the Chairman of GPB has, in general, departed from the strictness of the policies of the order, and applied principles consistent with the judicial standards of the *Dubilier* case. The fact that the total number of cases in which the Government has an interest has increased "alarmingly" since the issuance of the order, they explain, is probably due to the fact that the agencies felt "bound to make their determinations in accordance with the strict terms and intent of the order rather than under the more liberal rules of case law" (pp. 920–923).

Conclusion

Aided by the Department Patents Board, the Department has been constructive and thoughtful in the formulation of its patents policies. Implementation has been spotty, and in many cases weak, because of a lack of effective machinery of coordination.

The problems of patent policy, especially in departments like Health, Education, and Welfare, are primarily administrative rather than legal. Formulation of simplified procedures, and the conduct of an educational program on policy among top supervisors as well as research staff, could greatly reduce the load of detail, promote understanding, and reduce instances of noncompliance and delay. High-level attention needs to be given to problems of relationship with grantee institutions and to the terms of cooperation in contract research.

The machinery and procedures required under Executive Orders 10096 and 9865, as presently established, are entirely unproductive and an impediment to the administration of any clear-cut policy.

D. General Summary and Recommendations

The research activities of the Department of Health, Education, and Welfare are dedicated, not to the narrow interests of the Government, but to the general public interest. Free and full dissemination of the results of research, through every appropriate means, is essential to the vitality of the research effort and the enrichment of the common store of knowledge.

Inventions which are the outgrowth of such research should not, through patenting, be made the subject of exploitation for profit or for private ends.

The same basic principles are applicable to the research activities of the Department whether conducted directly, through grants to nonprofit organizations, or under contract with nonprofit or profitmaking organizations.

Under a foreign policy which favors the interchange of information in health and welfare fields the same basic principles are applicable to the foreign as well as the domestic rights.

A policy of disclosure by publication will generally be effective to protect the public interest against adverse claims of prior invention. Patent applications on inventions assignable to the Government will occasionally be desirable for defensive purposes. Patents generally, however, have no meaning except as instruments of economic control. The ownership of patents on inventions, particularly in the health field, has for the Government certain distinct disadvantages.

Patenting of inventions assignable to the Government as the employer as (*a*) a system of incentive awards for Government employees, or (*b*) as a system for regulation and control of the product is undesirable; the Government has other more direct, more modern, and more appropriate means for achieving such purposes.

The Government, under established policy governing the terms of the employment, should be entitled to the entire right, title, and interest (foreign as well as domestic) in all inventions made by a Government employee (*a*) during working hours, or (*b*) with a contribution by the Government of facilities, equipment, materials, funds

or information, or the services of other Government employees on official duty, or (*c*) bearing a direct relation to the official duties of the inventor, except that when the contribution of the Government has been so insubstantial that it is deemed clearly inequitable to require assignment of the entire right, the Government should be entitled to a nonexclusive, irrevocable, royalty-free license for all Government purposes.

Since patent administration is desirable only when necessary to protect the public interest, there is no objection to leaving the disposition of inventions arising from grants to, or contracts with, nonprofit institutions when they have policies which are *generally* compatible with the foregoing principles.

Similarly, there is no objection, in the individual case where the right of determination is reserved to the Department (or the head of a constituent organization in the Department), to leaving the rights to the nonprofit grantee or contractor when there is assurance that the disposition will be consistent with these principles.

There is no persuasive body of evidence, at least to date, that inventions to which the Department has taken assignments in behalf of the Government, or which have been dedicated to the public by publication, have failed of development because they have not been available for exclusive licensing. The exercise of such power by a governmental agency, such as this Department, would be fraught with special problems, such as the selection of licensees on a preferential basis, administration of the license agreement, seeming endorsement for public use of a product which may be inferior or dangerous if improperly used (especially unseemly in the case of a therapeutic product), compromise of the Department's own responsibilities as a regulating agency, danger of conflict with Government policies in other fields such as antitrust or foreign policy.

Such experience as has been accumulated under Department policy relating to grants, which permits leaving invention rights to grantees with the right to license exclusively (except as against the Government) in some cases where such is deemed necessary for development purposes, indicates that the need for exclusive licensing is rare and is generally limited to a period of 2 or 3 years.

The exception to standard Department policy, under the cancer chemotherapy program, by which the contractor may acquire the entire rights to inventions for which the Government has fully paid (subject only to a license to the Government and to the invocation of difficult march-in procedures in the event of demonstrated failure to meet health needs), represents a failure to date to enlist the full cooperation of major drug and chemical companies in an all-out attack on the most dreaded of human diseases.[117] If exceptions to basic

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[117] Compare "History of the Development of a Patent Policy," by Edwin T. Cohn of Harvard University, Harvard University Printing Office, April 1951, describing the working out of relations with industry during developmental phases of inventions regarding liver extract for treatment of pernicious anemias and plasma fractionalization. A letter from James Conant, president, on July 2, 1947, to J. L. Hunt, vice president, Armour Laboratories states the thesis on which satisfactory arrangements were concluded with the laboratories:

"The research conducted by the department of physical chemistry is financed in large part by funds given for the advancement of science for the benefit of the public and it would be most embarrassing for the university if inventions which are directly or indirectly the outgrowth of that research, particularly inventions in human therapeutic or public health fields, are made the subject of privately owned patents administered for profit and not for the benefit of the public."

policy are to be considered for a program of special exigency involving research contracts, the Department, while taking title, should have authority to contract for an exclusive license to the contractor for a strictly limited period and under the limitations deemed consistent with the public purposes of the program.

In the expenditure of public funds and in its growing role of leadership in the field of research for the general health, education, and welfare, the Department is properly concerned to preserve the integrity of its own research establishments and, in its relation with grantees and contractors, to establish standards which will assure to the scientific community and to the public the results of such research. Particular responsibility rests upon the Public Health Service to uphold, through its National Institutes of Health and its other research arms, the highest traditions of medical research.

The problems induced by the patent system, in relation to such programs, are primarily problems of policy formulation, education, and administrative coordination rather than of law. Procedures could be greatly simplified, and top-side attention secured for major problems of relationship to research employees, grantees, and contractors, through effective administrative coordination within the Department and elimination of needless reporting and review requirements under Executive Orders 10096 and 9865.

Legislation is desirable to set at rest the question of authority to fix the terms of employment for employees of the Federal Government with respect to rights in inventions arising from or in connection with their employment. If uniformity of rule is not consistent with the authorized programs of the various research agencies, the legislation should provide for such variations as are necessary to meet their specialized objectives.

Legislation is desirable also to authorize such filings in the Patent Office on Government-claimed inventions as will serve to protect the Government's claims against third parties, while obviating the need for full prosecution of patent applications in the absence of contest. Additionally, to prompt the making of determinations of rights, where necessary, and to protect the Government and the public, inventors who have been in Government employ should be required to state on their patent applications whether or not the invention was conceived or reduced to practice during the period of their employment by the Government, in order that a determination of Government rights, if any, in the invention may be made and recorded.

In connection with the general study of patent law attention should be given to the relation of the patent system to the field of therapeutic inventions with particular reference to the duration of permissible monopolistic control.

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APPENDIXES

APPENDIX A

REPORT OF FEDERAL SECURITY AGENCY COMMITTEE ON PATENT POLICY

On July 21, 1949, the Administrator appointed a committee to study the patent problems of the Agency and to formulate recommendations for an agencywide patent policy. The members of the committee are:

Miss Mary E. Switzer, Chairman.
Louis S. Baker, Social Security Administration.
W. W. Keesecker, Office of Education.
David E. Price, National Institutes of Health
Albert F. Siepert, alternate.
Dean Snyder, Office of Special Services
L. D. Elliott, Food and Drug Administration, alternate.
Robert C. Cassels, Office of the General Counsel.
Miss Gladys Harrison, Assistant General Counsel, met regularly with the committee.

In considering the policy to be developed, an inventory of the problems of the different units of the Agency made it clear that any agencywide policy should deal not only with the acquisition and disposition of rights in inventions developed by Agency employees, but also with those inventions resulting from research carried on outside the Agency by various arrangements such as grants under the Public Health Service's programs. In view of the agencywide membership on the committee and the varied situations familiar to its members, it was natural that some members questioned the possibility of studying the related problem of an Agency policy with respect to writings by Agency employees. The committee decided, however, that consideration of this subject should be postponed at least until the conclusion of the work on the patent question.

The patent problem is a real one, and may be expected to increase in magnitude as the number of discoveries expands under the accelerated medical research program. Although the Agency, as such, has lagged behind other agencies of the Government in the development of a patent policy, formal reporting of inventions has been required by the Public Health Service since 1940 in its grant-in-aid programs. Agency records indicate the handling of the patent rights to some 50 inventions within the Agency. Of these two-thirds involved the Public Health Service.

Before the appointment of the Agency Patent Policy Committee, two factors particularly had pointed up the need for the formulation of some authoritative guide for the constituent units of the Agency. The first was a report from the Department of Justice to the President recommending a governmentwide patent policy, and outlining the principles which should be incorporated therein. The second was the rapid growth of the research activities of the Public Health Service with the likelihood of an increasing number of inventions of potentially great importance to the public health and welfare.

The issuance of Executive Order 10096 on January 23, 1950, enunciating a patent policy for employees had an important influence on the work of the committee for it established broad policy principles, by which the committee was guided during its final meetings.

EMPLOYEE INVENTIONS

The committee decided to consider first the problems incident to employee inventions and to attempt to develop an agreed-upon policy in this field. At the outset of its discussions, the committee had to acquire considerable background in the whole field of patent problems and especially an understanding

of the legal situation with respect to patent rights as it exists in the absence of a stated policy. Under present law, in the absence of contractual arrangement to the contrary, the employer is entitled generally to no more than a shop right in an invention made by an employee, even though the invention may have been developed largely on working time and with the employer's facilities. Furthermore, the employer acquires no right at all if the invention is developed without such assistance, even though the invention may be connected with the work the employee was hired to do. It is only when the invention is a part of an employee's assigned duties that the law steps in, in the absence of special agreement between the parties, to recognize the employer as the true owner.

The committee had next to familiarize itself to some degree with the policies of other employing agencies, both public and private. As might be expected, these policies are most highly developed in fields which involve research or investigatory activities likely to result in new inventions, and employer-control of the inventive product of such activity is generally provided. Data from the Department of Justice reports and the personal knowledge of members of the committee gave a good basis for understanding.

In private industry, for instance, employment contracts which involve research almost invariably contain tight clauses which give the employer the ownership of all work-connected inventions of the employee. These clauses are designed not only to assure the employer the chance to exploit the invention for himself, or to suppress it if he chooses, but also to prevent the invention from being developed by potential competitors.

Research institutions and universities because of their scientific and educational purposes and agencies of the Government because of their responsibilities to the public, have had to consider quite different factors. While wide variations of policy exist, the policies of such agencies increasingly aim to assure the availability for general use and benefit of inventions arising from their activities. Among the civilian agencies of the Government, the Department of Agriculture over a long period and the Department of the Interior since 1942 have developed employee invention policies designed to protect the public interest by requiring assignment to the Government in most instances. To a substantial degree these policies were developed as the result of conspicuous instances in which the taxpaying public which had financed the work leading to an invention had to pay again in the form of royalties to private interests for its use.

In formulating a policy for an agency of the Government, there must be borne in mind the legal position which obtains when ownership of the rights to an invention is acquired by the Government. A private owner (whether he is the inventor himself or his assignee) is free through the device of a patent to restrict the use of an invention to his own purposes, to exploit it through exclusive or nonexclusive licensing, or to suppress its use entirely during the life of the patent. The Government, on the other hand, may dedicate an invention to the public or, if the invention is patentable, may obtain a patent and issue licenses for its use, but the primary purpose is to forestall the possibility of a patent being issued to someone who might by such means suppress or exploit the patent for private ends. A patent in the name of the Government as owner, therefore, is merely a means of assuring the availability of an invention to the public, subject only to such controls as may need to be attached to protect the public health and safety (as in the case of a dangerous drug or similar product).

The basic conclusion of the committee was that all inventions made by agency employees which are directly related to their official functions or to which the Federal Government has made a substantial contribution, should be owned and controlled by the Government for the public benefit. This conclusion is in accord with the basic recommendation of the Justice Department report. It was reached by the committee, however, only after a process of independent discussion in which diverse viewpoints yielded more and more to a growing sense of understanding of the problem and of conviction as to the basic principle to be followed in its solution.

The committee, moreover, gave great weight to their belief that special considerations apply in an agency, such as ours, which is devoted to programs concerned with welfare and health. Particularly in the case of employees engaged in scientific research or in the supervision of research activities, the committee felt that the nature of the work itself and the indivisible nature of the cooperative efforts in which research staffs are engaged warrant the requirement that the inventive product of staffs so engaged should belong to the Government. The committee was also of the view that, in the case of inventions in the field of health,

all doubt as to whether the Government contribution was sufficient to warrant the requirement of assignment should be resolved in favor of assuring the availability of the invention to the public. Many physicians and scientists take the position, as a matter of professional ethics that inventions in this field should belong to the public and not be made the subject of private exploitation.

The committee report on employee inventions was well in hand when a draft Executive order establishing a general policy on inventions by Government employees came to the Agency for comment. Executive Order 10096 was issued January 23, 1950.

This Executive order provides, basically, that the Government shall obtain the entire right and interest in all inventions made by an employee with a contribution of Government time or facilities or which bear a direct relation to his work. Title may be left to the employee, however, when the Government contribution to the invention or interest in it is "insufficient." The order sets forth a procedure for determining the disposition of ownership rights in such inventions. It states a presumption that the requirement of assignment applies in the case of inventions made by employees assigned to make improvements or conduct or perform research or development work or to superintend or review work of this nature. The presumption is otherwise in the case of employees whose work is not connected with such activities.

Because of the issuance of Executive Order 10096, the further work of the committee in developing its policy for employees was limited to recommendations for machinery and procedures within the Agency which would conform to one requirement of the Executive order. These are described in the draft of an Agency order attached to this report.

Inventions Arising From Research Grants or Contracts

This field, although included in the previous Department of Justice report, is not covered by the recent Executive order.

In the formulation of a policy the committee agreed that the controlling consideration is the purpose which underlies all research activities conducted in or sponsored by the Agency. This is the advancement of knowledge and development of techniques for use as broadly as possible for the public health and welfare. The dissemination of information as to research and its practical application is a specific duty of the Public Health Service under its basic legislation. The position of the Agency in this respect is quite different from that, for example, of the Department of Defense whose vast programs of research and development have as their primary purpose the development of devices and techniques for use by the military and its suppliers.

The principle governing the patenting of inventions developed in the course of research arrangements should be basically the same as in the case of employee inventions. However, in the committee's view some differences in implementation are desirable because of differences in the arrangements under which the inventor works. In the case of an employee the terms and conditions of his employment are subject to general rules and control by the Government.

In the case of a grant of research funds to an individual (who will in no case be an employee of the Agency), the individual may be working independently, or may be associated with others working as a group, or may be attached to an institution which controls many of the conditions of his work. Grants are also made to institutions which, like the Public Health Service, carry on extensive research operations, and are themselves the employers of research workers and sponsors of projects. Many of these institutions will have well developed policies of their own with respect to the handling of patent rights in inventions developed in the course of their research activities, and in many cases the contribution of the Federal Government to inventions which may develop may be relatively minor.

Since 1940 the Public Health Service has dealt with the problem of patent rights in inventions made under its grant and fellowship programs by making its awards subject to the following condition:

"If any patentable discoveries or inventions are made in the course of work aided by any grant received as a result of this application, the applicant will, in consideration of such grant, refer to the Surgeon General of the Public Health Service, for determination, the question of whether such patentable discoveries or inventions shall be patented and the manner of obtaining and disposing of the proposed patents in order to protect the public interest."

The committee recommends that the proposed Agency order should provide that conditions similar to this, reserving a right of determination to the grantor, be included in all grants and contractual arrangements for research purposes. The purpose of the provision is to provide a means of assuring that the inventive product of research aided under research programs of the Agency are made freely available to the Government, to science, to industry, and to the general public, subject only to such conditions as may be required to protect the public interest.

The principal need, however, is the establishment by the Agency of a guide for the exercise of the discretion thus reserved. Such a guide is needed (1) administratively, to assure consistent actions within the Agency; (2) in fairness to the institutions with which we deal in relation to collaborative research work or research grant, so that they may know the principles which will be followed in determinations as to patenting and the disposition of rights; and (3) for the information of the public. The committee, moreover, was impressed by the fact that any policy established by the Federal Security Agency at this time may well have a significant influence on the shaping of policies by other institutions engaged in research for noncommercial purposes. Some of these (as for example, Chicago University, Yale University) have adopted the general policy that neither the university nor members of its faculty shall in any way profit from inventions made in connection with work connected with the institution. Others (such as Columbia and Wisconsin) leave individual faculty members free to assign or not to assign rights to the institution but encourage assignment of rights to a research body set up by the university to secure patents in appropriate cases and to administer such rights on a licensing and revenue-producing basis.

Obviously, the vital question in the case of cooperative projects is not so much whether rights are required to be assigned to the Government or to any other body but whether rights to the invention, however assigned, will be so administered that the invention will be readily available to the public, to science, to the Government, and to industry.

The committee recommends as a general rule that the right of determination, which the Agency will reserve in its research grants and contracts, be exercised so as to require assignment to the Government. The committee recognizes that the circumstances of support of most of the projects aided by grants from the Agency place them in the group of cooperative projects in which exceptions to this general rule will be made. Therefore, it would allow exception when the invention has been developed as a cooperative project or with substantial independent contribution from other sources. The exception would be subject to the condition that the grantee or contractor give adequate assurance that the invention will be effectively dedicated to the public or, if the invention is to be patented and made available on a licensing basis only, that such licenses shall be nonexclusive, royalty free, and unconditional. This recommendation is in accord with the Department of Justice report as a matter of basic principle but represents a departure in the latitude afforded to leave rights to the invention to the contractor or grantee in appropriate circumstances. However, later thinking in the Department of Justice on this point is in line with our recommendation.

Members of the committee in addition felt that there might occasionally be situations in which it may appear that the effective development of an invention of potentially great significance may be prevented or delayed unless exclusive control of the invention can be permitted for a temporary period for purposes of development and exploitation. This may be true particularly in cases where the value of the invention depends upon its utilization in connection with others controlled by patents already in private hands. The recent situation involving a process which would expedite the production of cortisone was cited. On the other hand, members of the committee also recognized the difficulty of informed forecast and judgment in matters involving commercial development, the dangers inherent in any action by a Government agency giving a preference to any private interest in inventions financed even in part by the Government, and the possible strengthening of a monopolistic interest in a particular field by organizations already controlling patents in that field.

As drafted, however, the proposed Agency order provides that in the case of inventions resulting from cooperative research or to which substantial contribution has been made by others, rights to the invention may be left to the grantee without the general limitations indicated above but on the condition that rights

to the invention are to be assigned to a qualified organization for a limited period for the purpose of developing and exploiting the invention, that the terms of the assignment are to contain reasonable safeguards against unreasonable royalties or repressive practices, and that it is found that by such assignment the fruits of the invention may be made available to the public more quickly, more economically, in larger quantity or better quality. It is provided, however, that such action may be taken only in exceptional circumstances and with the express approval of the Administrator.

In all cases where an assignment to the United States is not required, it is recommended, of course, that as a minimum there be assigned to the Government an irrevocable, nonexclusive, royalty-free right to use the invention, with power to grant sublicenses for all governmental purposes. There is also reserved, in accordance with Executive Order 9865, the exclusive right to file foreign patent applications thereon, with only minor exceptions.

June 7, 1950.

APPENDIX B

[Manual: General Administration. Part 6. Patents and Inventions]

CHAPTER 6–10

REGULATIONS AND PROCEDURES

TITLE 45—PUBLIC WELFARE

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 6—INVENTIONS AND PATENTS (GENERAL)

PART 7—EMPLOYEE INVENTIONS

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

The following parts are Department rules and policies relating to inventions which are made by Department employees having a relation to their official duties or with some contribution from the Government or which arise from research or related activities assisted by grants or otherwise under programs administered by the Department.

PART 6—INVENTIONS AND PATENTS (GENERAL)

Sec.

AUTHORITY: §§ 6.0 to 6.6 issued under Reorg. Plan No. 1 of 1953, 18 F.R. 2053; 3 CFR, 1953 Supp., E.O. 10096, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 6.0 *Definitions.* As used in Parts 6, 7, and 8 of this subtitle:

(a) "Department" means the Department of Health, Education, and Welfare.

(b) "Secretary" means the Secretary of Health, Education, and Welfare.

(c) "Head of constituent organization" includes the Surgeon General of the Public Health Service, the Commissioner of Education, Commissioner of Social Security, Commissioner of Food and Drugs, the Director of Vocational Rehabilitation, and the Superintendent of Saint Elizabeths Hospital.

§ 6.1 *General policy.* Inventions developed through the resources and activities of the Department are a potential resource of great value to the public health and welfare. It is the policy of the Department:

(a) To safeguard the public interest in inventions developed by Department employees, contractors and grantees with the aid of public funds and facilities;

(b) To encourage and recognize individual and cooperative achievement in research and investigations; and

(c) To establish a procedure, consistent with pertinent statutes, Executive orders and general Government regulations, for the determination of rights and obligations relating to the patenting of inventions.

§ 6.2 *Publication or patenting of inventions.* It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public through publication. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made only if the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Chairman of the Government Patents Board. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

§ 6.3 *Government-owned patents; licensing; dedication to the public.* All licenses under patents and pending patent applications for the administration of which the Department is responsible shall be issued by the Secretary. Licenses will be royalty-free, revocable and nonexclusive. Except in unusual cases when determined upon recommendation of the head of the constituent organization that unconditional licensing would be contrary to the public interest, licenses will be issued to all applicants and will contain no limitations or standards relating to the quality of the products to be manufactured, sold, or distributed thereunder. To reduce the need for individual license applications, patents held for unconditional licensing shall be dedicated to the public as may be feasible.

§ 6.4 *Central records; confidentiality.* Central files and records shall be maintained of all inventions, patents, and licenses in which the Department has an interest, together with a record of all licenses issued by the Department under such patents. Invention reports required from employees or others for the purpose of obtaining determinations of ownership, and documents and information obtained for the purpose of prosecuting patent applications shall be confidential and shall be disclosed only as required for official purposes or with the consent of the inventor.

§ 6.5 *Procedures relating to employee and grantee inventions.* The Department Patents Officer, with the approval of the Department Patents Board, and the heads of constituent organizations within their respective areas of responsibility, are authorized to issue such procedures and bulletins and take such other actions as may be necessary or desirable to supplement the provisions of Parts 7 and 8 of this subtitle.

§ 6.6 *Issuance of patents on non-fee basis; certification of public interest.* For the purpose of an application for a patent to issue under the non-fee provisions of the Patent Code (35 U.S.C. 266), a certification that an invention is used, or is likely to be used, in the public interest may be executed in behalf of the Secretary by the head of the constituent organization having administrative jurisdiction over the inventor.

PART 7—EMPLOYEE INVENTIONS

Sec.
7.0 Who are employees.
7.1 Duty of employee to report inventions.
7.2 Determination as to patentability.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.5 Determination as to patenting.
7.6 Department review and determination.
7.7 Notice to employee of determination.
7.8 Employee's right of appeal.

AUTHORITY: §§ 7.0 to 7.8 issued under Reorg. Plan No. 1 of 1953, 18 F.R. 2053; 3 CFR, 1953 Supp., E.O. 10096, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 7.0 *Who are employees.* As used in this part, the term "Government employee" means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Chairman of the Government Patents Board, that to include him or them would be impracticable or inequitable, giving the reasons therefor. A person shall not be considered to be a part-time employee or part-time consultant for this purpose unless the terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

§ 7.1 *Duty of employee to report inventions.* Any Department employee is required to report promptly to the constituent organization in which he is employed any invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds or information, or of time or services of other Government employees on official duty. Reports of inventions (except for cases as to which it is decided by the appropriate office or constituent organization, with the concurrence of the Department Patents Officer, that it does not appear they are or may be patentable) shall be forwarded through appropriate channels to the head of the office or constituent organization having administrative jurisdiction over the inventor at the time the invention was made. Thereafter they shall be forwarded with the related administrative recommendations and determinations to the Department Patents Officer.

§ 7.2 *Determination as to patentability.* Upon receiving a report of an employee invention, the head of the appropriate office or constituent organization shall make in writing the decision on behalf of the Department as to whether the result of the research, development or other activity constitute an invention or inventions which may be patentable.

§ 7.3 *Determination as to domestic rights.* The determination of the ownership of the domestic right, title, and interest in and to an invention which is or may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the head of the appropriate office or constituent organization, in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Chairman of the Government Patents Board, as follows:

(a) The Government as represented by the Secretary shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire domestic right, title, and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest, therein (although the Government could obtain same under paragraph (a) of this section) the Department, subject to the approval of the Chairman, shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation, in the terms thereof, to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b) of this section, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (1) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (2) to conduct or perform research, development work, or both, (3) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (4) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, falls within the provisions of paragraph (a) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b) of this section. Either presumption may be rebutted by the facts or circumstances attendant upon the conditions under which any particular invention is made and, notwithstanding the foregoing, shall not preclude a determination that the invention falls within the provisions of paragraph (d) of this section.

(d) In any case wherein the Government neither (1) obtains the entire domestic right, title and interest in and to an invention pursuant to the provisions of paragraph (a) of this section, nor (2) reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (b) of this section,

the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

§ 7. *Option to acquire foreign rights.* In any case where it is determined that all domestic rights should be assigned to the Government, it shall further be determined, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, that the Government shall reserve an option to require the assignment of such rights in all or in any specified foreign countries. In case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

§ 7.5 *Determination as to patenting.* When the head of the appropriate office, or constituent organization determines in accordance with the provisions of §§ 7.3 and 7.4, that the Government has rights in a patentable invention:

(a) He shall also determine whether the Department should seek to obtain a domestic patent thereon, or whether it shall be published or other action taken in the public interest, giving his reasons therefor; and

(b) He shall further recommend in writing whether the invention should receive foreign patent protection or be published abroad and, if affirmative, should specify the foreign jursidictions in which action is recommended, giving reasons therefor, and should indicate, if possible, its immediate or future industrial, commercial, or other value, including particularly its value to public health.

§ 7.6 *Department review and determination.* The determination by the head of an office or constituent organization of the ownership of domestic or foreign rights in an invention by a Department employee shall constitute the decision of the Department unless, upon review, the Department Patents Officer questions the consistency of the determination with applicable law or regulations or with Department policy. Any question, unresolved after consultation with the originating unit, will be submitted by the Department Patents Officer to the Department Patents Board which shall either affirm or reverse the determination or return the same to the head of the constituent organization or office for further action. If the Board proposes to determine, or to approve a determination, that the invention shall be required to be assigned to the Government, it may in its discretion afford the employee an opportunity of a hearing.

§ 7.7 *Notice to employee of determination.* The appropriate office or constituent organization shall notify each employee-inventor in writing, of the Department's determination and of his right of appeal, if any. In the case of determinations made by the Department Patents Board, the notification shall be made by the Department Patents Officer. Notice need not be given if the employee stated in writing that he would agree to the determination of ownership which was in fact made.

§ 7.8 *Employee's right of appeal.* An employee who is aggrieved by a determination of the Department may appeal to the Chairman of the Government Patents Board, pursuant to section 4(d) of Executive Order 10096 and regulations issued thereunder, by filing a written appeal with the Chairman, in quadruplicate, and a copy of the appeal with the Department Patents Officer, within 30 days (or such longer period as the Chairman may, for good cause, fix in any case) after receiving written notice of such determination.

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

Sec.
8.0 Policy.
8.1 Conditions to be included in research grants.
8.2 Determination of domestic rights.
8.3 Licenses to the Government.
8.4 Option to acquire foreign rights.
8.5 Fellowships.
8.6 Contracts for research.
8.7 Cancer chemotherapy industrial research contracts.

AUTHORITY: §§ 8.0 to 8.7 issued under Reorg. Plan No. 1 of 1953, 18 F.R. 2053; 3 CFR, 1953 Supp., E.O. 9865; 12 F.R. 3907; C CFR, 1947 Supp., E.O. 10096, 15 F.R. 391; 3 CFR, 1950 Supp.

§ 8.0 *Policy.* (a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees, to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a untilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 *Conditions to be included in research grants.* Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide, as the head of the constituent unit may determine, either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the head of the constituent unit responsible for the grant, or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the head of the constituent unit finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be prescribed, to file foreign patent applications upon the invention.

§ 8.2 *Determination as to domestic rights.* Rights in any invention not subject to disposition by the grantee pursuant to paragraph (b) of § 8.1 are for determination by the head of the constituent organization as follows:

(a) If he finds that there is adequate assurance that the invention will either be effectively dedicated to the public, or that any patent which may be obtained thereunder will be generally available for royalty-free and nonexclusive licensing, the effectuation of these results may be left to the grantee.

(b) If he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary.

(c) If he finds that the interest of another contributing Government agency is paramount to the interest of the Department of Health, Education, and Welfare, or when otherwise legally required or in the public interest, the invention may be left for disposition by that agency in accordance with its own policy.

(d) In all other cases, he shall require that all domestic rights in the invention shall be assigned to the United States unless he determines that the invention is of such doubtful importance or the Government's equity in the invention

is so minor that protective measures, except as provided in § 8.3, are not necessary in the public interest.

§ 8.3 *Licenses to the Government.* Any arrangement or determination as to the disposition of rights in inventions pursuant to § 8.1, § 8.2, § 8.5 or § 8.6 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

§ 8.4 *Option to acquire foreign rights.* In any case where it is determined that all domestic rights should be assigned to the Government, there shall be reserved to the Government, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, an option to require the assignment of all rights in the invention in all or in any specified foreign countries. In any case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to sublicense for all governmental purposes.

§ 8.5 *Fellowships.* In the discretion of the head of the responsible constituent organization, the award of a fellowship to a person not a Government employee may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of paragraph (a) of § 8.1, or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which meet the requirements of paragraph (b) of such section.

§ 8.6 *Contracts for research.* (a) Contracts for research, with other than nonprofit institutions, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the head of the constituent organization responsible for the contract, for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication of the public. In the exercise of this power the organization head will be guided by the policy specified in § 8.2 with respect to grants.

(b) Contracts for research with nonprofit institutions shall contain provisions as in paragraph (a) of this section except that, if it is determined that the institution's policies and procedures are acceptable as meeting the requirements of § 8.1(b) with respect to grants, the contract may provide, with such special stipulations in the contract as may be deemed necessary in the public interest, for leaving the ownership and disposition of all domestic rights for determination by the contracting institution in accordance with such policies and procedures.

§ 8.7 *Cancer chemotherapy industrial research contracts.* Notwithstanding the provisions of § 8.6, the Surgeon General in the negotiation of contracts with other than nonprofit organizations for the cancer chemotherapy research program shall be subject only to such limitations and alternatives as the Secretary may approve for such program.

(6–10–20)

PATENT POLICY APPLICABLE TO CANCER CHEMOTHERAPY INDUSTRIAL RESEARCH CONTRACTS

A. *General*

1. The cancer chemotherapy program of the Public Health Service is an intensified effort, with special appropriations made available under a Congressional directive, to explore exhaustively and rapidly the potentialities of chemical compounds in the control of cancer. Because of the peculiar exigencies of this program and in order that the resources of pharmaceutical and chemical firms may be brought to bear with a minimum of delay, certain exceptions to general Department policy will be permitted in the negotiation of industrial contracts for this program.

2. Industrial research contracts for this program may contain either:

a. the standard patent clauses, reserving to the Surgeon General the right to determine the disposition of inventions arising from the performance of the contract or, in lieu of such right,

b. standard alternative clauses leaving the right to patent and exploit such inventions with the contractor, subject to certain limitations deemed necessary to protect the public's interest in the results of the contracted research.

3. Department policy concerning the negotiation and operation of the alternative clauses:

a. *Contract negotiations:* The alternatives indicated will be made available in the negotiations with all contracting companies without discrimination.

b. *Public interest:* The operation of these alternative clauses will be closely reviewed to assure that the following basic objectives are maintained in the public interest:

(1) The availability of information concerning the results of research and the right, without undue delay, to make disclosures to the extent essential to serve the research need;

(2) The availability for development and use of health purposes, on reasonable terms, of inventions arising from the research contract, whether actual development and production is to be made by the contractor himself or by others; and

(3) Sustained concentration on the anti-cancer objective of all resources mobilized for the purposes of the contract.

c. *Contractor's interests:* The Surgeon General or his representatives shall maintain close consultations with the contractor concerning questions affecting the public need for the products of inventions which are subject to the limitations prescribed in the alternative clauses for the protection of the public interest with respect to their supply, price, and quality. The objective of these consultations shall be to promote a mutual awareness of such matters in order to assure to the contractor (under his right to exploit the invention) an opportunity on his own initiative to take such actions regarding them as he believes would be in his and in the public interest.

B. *Contracts for research—Rights left to contractor*

When the contract is for research (including contracts for product development necessary for purposes of research) to be performed by the company (with or without provision for subcontracting), the contract, as an alternative to the standard patent clauses, may provide for leaving to the contractor the right to patent and exploit any invention conceived or first actually reduced to practice in the course of the performance of the contract subject, however, to the following limitations which are deemed necessary to protect the public interest:

1. *Reporting.* Agreement that the contractor will report promptly to the Surgeon General any such invention and will also report promptly the filing of any domestic or foreign patent application thereon or his election not to file such application. Invention Report shall be required after the conception or first actual reduction to practice of each invention that reasonably appears to be patentable and, in any event, as soon as any evidence of utility has been developed (whether in a health or other field of use).

2. *Disclosure.* Reservation to the Surgeon General of the right to make disclosure of the invention, whenever he deems it in the public interest, after taking into consideration a reasonable opportunity to the contractor to protect such rights as he may have in the invention. The contract may specify that such disclosure shall not in any case, without the consent of the contractor, be made in less than six months from the time the Surgeon General determines the invention was or should have been reported.

3. *License to the Government.* Reservation to the Government of an irrevocable, nonexclusive, royalty-free license to practice or cause to be practiced, by or for the Government throughout the world, each subject invention (whether patented or unpatented) in the manufacture, use or disposition according to law of any article or material or in the use of any method or process.

4. *Failure to meet health needs.*

a. In recognition of the Government's investment and the public interest in the results of contracted research, agreement that whenever, subsequent to the contractor's filing of a patent application for any invention conceived or first actually reduced to practice in the course of the performance of a contract, the Surgeon General, after obtaining and considering the advice of such advisory bodies or consultants as he deems appropriate and competent, has ground to believe that such invention, whether related to a product, process, or otherwise, is at such stage of development that if it were more

generally available it would meet a health need and that the public interest[1] requires the invention to be available for health purposes to others than the contractor and his licensees, he shall so notify the contractor, giving reasons therefor, and request him, within a time specified, to take appropriate steps to meet the public need, which may include the issuance of licenses to additional manufacturers of the contractor's own selection. (Such requests shall be supplementary to such informal consultations between the Surgeon General or his representative and the contractor as have taken place in accordance with the provisions of section A.3c above.)

b. If, upon expiration of the time specified, or such extension thereof as approved by the Surgeon General, the Surgeon General finds that the contractor has failed to take appropriate steps adequate to meet the public need, he shall notify the contractor, with reasons therefor, that at the end of 90 days from such notice he will exercise the rights specified below. If within 20 days of receipt of such notice the contractor fails to file a written request for a hearing as provided below, the Surgeon General shall upon expiration of the above 90-day period have the right:

(1) to dedicate to the public all rights in the invention[2] or;

(2) to issue (under or in anticipation of the issuance of any such patent) nonexclusive, royalty-free licenses (for practice of the invention for any health purpose) on a nondiscriminatory basis to all qualified applicants to use, manufacture and sell embodiments of the invention for any health purpose.[3]

c. If, within 20 days of receipt of notice, the contractor files such request for a hearing, the Surgeon General, or a representative or representatives designated by him for this purpose, shall afford the contractor a reasonable opportunity to be heard, to be represented by counsel, to present any pertinent information and argument, and to rebut any other information to be considered in reaching a decision. The findings by the Surgeon General or such representative(s) shall be in writing, shall be based solely on the material presented at the hearing, and shall be final and binding on the contractor. If the Surgeon General's decision based on these findings be that the contractor has not met the public need and that public dedication or additional licensing by the Surgeon General is necessary in the public interest, he may so dedicate or license, effective at the end of the above-provided 90-day period or at the conclusion of the hearing, whichever is later.

5. *Contractor's determination not to patent—Failure to pursue application.* Agreement that in the event the contractor elects, within a period (not to exceed six months after the invention was or should have been reported) specified in the contract, not to file a patent application on the invention, or, having elected to file thereafter fails to file and diligently prosecute a patent application, the Surgeon General, when he deems it necessary in order to protect the availability of the invention for health purposes, shall have the right to require the assignment to the Government of all domestic rights therein except for the reservation of a nonexclusive royalty-free license to the contractor.

6. *Foreign Rights.* Similarly, agreement that if the contractor fails to file, or elects not to file, foreign patent applications which the Surgeon General determines are necessary to protect the availability of the invention for health purposes in other countries, the Surgeon General may require the assignment of the foreign rights.

7. *Renegotiation on new leads.* (Such a provision not mandatory.) The contract may provide that if, in the course of the performance of the contract, the contractor identifies any new lead which it wishes to develop at its own expense, without utilization of facilities financed by the Government, the Surgeon General may, when he deems it consistent with advancement of the research purposes of the Government, renegotiate the application of the patent provisions of the contract to such new lead. Any modification of the terms of the contract shall be upon such consideration (which may be used to reduce the obligation of the Government under the contract) as the Surgeon General may deem equitable under the circumstances, after taking into consideration the extent of the investment of the Government in relation to the probable cost of further development.

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[1] With respect to supply, quality, or price.

[2] Such dedication to be effective against the contractor and any persons claiming from him upon filing by the Surgeon General with the Commissioner of Patents of notice of same.

[3] Either one or both of these alternatives shall be specified in the contract.

C. *Contracting with suppliers for screening and testing only*

1. When a company furnishes, for controlled screening and testing only, compounds or products not otherwise available to the Service and in which the company has a proprietary interest, the contract may provide that all rights in the compound or product shall remain in the company. It may additionally provide for confidentiality of the results for a limited period after the completion of the screening process and the report of the results by the Service to the supplier. Such period, as to results deemed significant for the research purpose, shall not exceed 12 months.

2. When the screening and testing of compounds obtained from the supplier under such a contract is carried out by an outside laboratory, the contract of the Service with the laboratory will contain provisions to safeguard the rights of the supplier under its contract with the Service.

D. *Inventions by Federal Employees*

Inventions made by Federal employees, or by Federal employees jointly with others, are subject to determination under applicable Executive Orders and Department regulations. Appropriate reference to this requirement will be made in connection with contracts with suppliers of chemical compounds for use in research to be conducted by the Service, and contracts for research and development in which Federal employees may in any way participate.

E. *Background patents or rights*

Nothing in this policy statement shall be deemed to limit the authority of the Surgeon General to negotiate for a license or other rights under existing patents or involving the use of patented or unpatented compounds or processes, as he may deem necessary for the effective prosecution of the cancer chemotherapy program.

CHAPTER 6–20

DEPARTMENT PATENTS BOARD AND PATENTS OFFICER

6–20–10 ORGANIZATION

A. The Department Patents Board shall consist of a chairman and six other members of the Department appointed by the Secretary.

B. The Department Patents Officer shall be appointed by the Secretary and shall serve as a member of the Board if so designated by the Secretary. A Deputy Department Patents Officer may likewise be appointed.

6–20–20 ASSIGNMENT OF RESPONSIBILITIES

A. The Department Patents Board shall:

1. Advise and consult with the Secretary and with appropriate Department personnel, including the Department Patents Officer and the Department's representatives on the Government Patents Board, on questions of patent policy affecting the Department.

2. Upon request, consult with and make recommendations to the Secretary, the Department Patents Officer, or the head of an operating agency, regarding the application of patent policies or procedures within the Department, or with respect to specific inventions.

3. In its discretion, after affording opportunity for an informal hearing, hear and determine on behalf of the Department, appeals from determinations relating to the ownership or patenting of employee inventions.

B. The Department Patents Officer shall:

1. Act as executive officer and secretary for the Department Patents Board.

2. Act either as the representative of the Department or as its alternate representative on the Government Patents Board, as designated by the Secretary; act as liaison officer for the Department with the Chairman of that Board and make such reports to him as may be appropriate; except where otherwise provided by the Secretary, represent the Department on

any boards and committees and in other matters relating to inventions and patents.

3. Act as liaison officer for the Department with the Department of Justice on matters relating to patent policies and procedures.

4. Receive all determinations made by the heads of operating agency units relating to inventions made by Department employees, referring, if necessary, any such determinations to the Department Patents Board for its review and decision.

5. Receive for transmittal, with his recommendation where appropriate, matters relating to patents requiring consideration or action by the Department Patents Board or the Secretary.

6. Consult and advise, as feasible, with the various operating agency organizations and officers of the Department in the formulation and carrying out of policies and procedures relating to inventions and patents.

7. Be responsible for the maintenance of records concerning Government-owned patents for the administration of which the Department is responsible and for the handling of applications for licenses thereunder.

CHAPTER 6-30

CRITERIA FOR PATENTING OR PUBLICATION—PROOF OF INVENTION

6-30-00 PURPOSE

This chapter provides supplementary criteria for Department personnel who are charged with responsibility for making recommendations as to the patenting or publication of inventions in which the Department has an interest (45 C.F.R. 7.5). It is issued, with the approval of the Department Patents Board, pursuant to Department Regulations (45 C.F.R. 6.5).

6-30-10 GENERAL ASSUMPTIONS

A. The Department's interest in inventions is almost the reverse of that which generally prompts a private patent application. Its concern is not to withhold the invention from the public or to charge royalties for its use but to assure the availability of the invention to all (45 C.F.R. 6.2). This assurance with respect to an invention may be lost if an individual claiming priority of invention files a patent application.

B. The Department therefore does have an interest, and under Executive Order 10096 it has an obligation, to take appropriate defensive action, to protect the interest of the Government and the public against potential adverse claims. Such action may take the form of initiating a patent application or by full disclosure through publication.

C. Since not all inventions are of sufficient importance to warrant the labor and expense of patenting, and since the Department does not itself maintain staff or facilities for such purpose, the need for patenting and the resources available for handling a patent application need to be weighed carefully before a determination as to patenting is made.

6-30-20 DETERMINATION AS TO PATENTABILITY

A. No recommendation as to patenting should in any case be made unless it is first determined that the invention may be patentable.

B. The determination as to whether the invention "may be patentable" should identify the originality of concept, as well as the elements of novelty and usefulness, believed to be present in the invention. This is for the reason that, even though an invention is "new and useful" it is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which the subject matter pertains" (35 U.S.C. 103).

C. Whether it is determined that the invention may or may not be patentable, the basis for the conclusions reached should be indicated in the determination. For example, a written report on these points by research workers who have familiarity with the art in the particular field is valuable, because it may indicate that the invention has been fully anticipated. In any event, the report itself will constitute a record bearing on the relation of the invention to the prior art, and so may serve a protective purpose.

D. The determination should set forth fully the dates of conception and of reduction to practice (or of the successful test or performance) of the invention, and of any prior disclosure (speeches, writings, printed publication, etc.) or use thereof. These are important because the invention will not be patentable if at the time of the determination it has been for more than one year either—

1. described in a printed publication in this country or abroad; or
2. in public use or on sale in this country (35 U.S.C. 102(b)).

6-30-30 INVENTIONS OF TRIVIAL VALUE OR SIGNIFICANCE

A. Unless "useful" to some degree, the invention will not be patentable.

B. Even though the invention is possibly patentable, it may be recommended that title be left with the inventor, pursuant to section 7.3(b) of the Department Regulations on grounds of "insufficient interest," subject to license to the Government under any patent which may be secured.

C. Government "interest" has two aspects. First, the Government has an interest as a potential user of the invention in its own operations or as a purchaser of products embodying the invention. Second, it has an interest (particularly strong in the field of research) of preserving for the public the products of its work and investment. Ordinarily, therefore, a recommendation of dedication to the public by publication rather than a finding of insufficient interest is appropriate in the case of all but patently trivial gadgets in which there has been no substantial investment of Government time or facilities.

D. Determinations of "insufficient interest" are subject to review by the Chairman of the Government Patents Board.

6-30-40 INVENTIONS OF SUBSTANTIAL VALUE OR SIGNIFICANCE

A. In general patenting should not be recommended when printed publication of a technically adequate description can be, or has been, arranged, or disclosure to or use by others can be, or has been, arranged under safeguards which will assure the availability of proofs as to time of conception, reduction to practice, and disclosure. (A person is not entitled to a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. 102(a).) Certainly patenting should not in the absence of unusual justification be recommended if the one year period which may elapse between a printed publication and the filing of an application has almost elapsed.

B. Patenting, however, is appropriately recommended when—

1. It is deemed advisable, in the case of an invention of high potential significance to the public health, safety, or welfare, to obtain maximum assurance against potential rival claims by establishing priority of invention and diligence in reducing to practice; or
2. It is deemed advisable, for reasons of health or safety, to retain control (beyond that afforded under the Federal Food, Drug, and Cosmetic Act, as amended, or the Public Health Service Act, as amended, or other Federal control legislation) of the invention itself, with legal authority to impose restrictive conditions on its use; or
3. other Federal agencies have such interest in the invention that they would be prepared to prosecute the patent application.

C. 1. Filing may be especially important as a protective device when there is likely to be a considerable lag between conception and actual reduction to practice and the invention is in a highly competitive field or when the invention is a basic one likely to constitute a key to subsequent advances in the art.

2. The filing of a patent application may be of great practical importance in case of competing claims because the Commissioner of Patents is under a duty to give notice and have questions of priority determined by a board of patent interferences whenever an application is made which would seem to interfere with any pending application or any unexpired patent (35 U.S.C. 135).

3. "In determining priority of invention there shall be considered not only the respective dates of a conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, for a time prior to conception by the other" (35 U.S.C. 102(g).

4. If a patent has issued, the filing of an allowable application is regarded in litigation involving priority of invention as a constructive reduction to practice and as evidence that the inventor made his invention at least as early as the date of filing.

D. The inventor's interest, as a matter of prestige and professional reputation, in having a patent issued in his name does not justify a recommendation for a patent application to be prosecuted at the expense of the Government.

E. In order that final determinations as to ownership may not be delayed pending resolution of the question of patenting, the operating agency may make a determination to patent contingent upon the availability of timely arrangements for the prosecution of a patent application, with reliance, in the event that these are not feasible, upon publication to protect the public interest.

6-30-50 PUBLICATION AS AN ALTERNATIVE TO PATENTING—"PRINTED" PUBLICATION

A. Publication, to be effective as an anticipation, requires a full disclosure setting forth the essential elements of the invention, and the manner of making and using it.

B. Such publication may be made in a technical journal or digest, in a publication of the operating agency (e.g., Public Health Reports, Social Security Bulletin) or in any other printed publication.

C. Additionally, the Office of Technical Services in the Department of Commerce, through the monthly publication of "U.S. Government Research Reports," provides a means of achieving technical "publication" as well as a means of disseminating papers which disclose the results of research. Original reports filed with the Office of Technical Services are deposited in the Library of Congress and copies may be ordered from the Library in photocopy or microfilm. In addition, Office of Technical Services is prepared to distribute stock copies of scientific research reports for government agencies. Listing in "Research Reports", together with the deposit of a typewritten or other copy in an appropriate Federal library, and published announcement of a means provided for duplication of copies for the public have been held to constitute "printed publication" under 35 U.S.C. 102(b). An operating agency wishing to avail itself of this channel should communicate with the Chief, Technology Division, Office of Technical Services, Department of Commerce.

6-30-60 NOTEBOOKS AND ORIGINAL RECORDS—EVIDENCE OF INVENTION

A. Whether or not a patent application is filed, written records, and particularly original records, properly dated, are important evidence of invention both as to completeness and the time when made. When these exist they may be used defensively to prevent the issuance of a patent on an invention subsequently conceived, or to contest the validity of a patent which may have been granted to some other person. For such purpose, the conception should be recorded, with indication of the date of conception, and immediately corroborated by communication to a competent witness who may be asked to read and initial the record, indicating the date of his initialing. Reduction to practice should be corroborated by a witness who observes the actual test or performance. Accurate dating is an essential factor in such records.

B. The operating agency, to the extent deemed consistent with good research practice, should require of its research workers the making and preservation of records which will serve a probative purpose. This is especially desirable in the case of developments falling within section 6-30-40.B1.

APPENDIX C

(10/19/56)

MANUAL GUIDE—GENERAL ADMINISTRATION

HEW No. 1

PATENTS AND INVENTIONS

1. PURPOSE

This guide summarizes the rights and duties of employees with respect to inventions which they may make while in the employ of the Department. This guide is of particular concern to employees engaged in research, since their work is of such a nature that they are most likely to develop patentable inventions. All employees, however, should be aware that regulations exist with respect to such inventions.

2. REGULATIONS

A. *Government-wide.* Uniform requirements applicable to all Government employees for determining the ownership of inventions made after January 23, 1950, were established by Executive Order 10096. The provisions of Order 10096 are administered by the Chairman of the Government Patents Board. Regulations supplementing the Executive Order have been issued by the Chairman in the form of Administrative Orders, together with interpretations and other procedural instructions.

B. *Department.* Department regulations, published in the Federal Register (20 F.R. 6747), supplement these directives for purposes of application to this Department. These regulations (45 C.F.R. 6.0 to 8.5) are reproduced in Part 6 of the General Administration Manual. Sections 7.0 to 7.8 of those regulations deal specifically with employee inventions.

3. DEPARTMENT POLICY

It is Department policy that the results of Department research should, as a rule, be made widely, promptly, and freely available to the public. Often this availability will be adequately preserved through dedication of the invention to the public by publication. At times, however, it may best be assured by the control that comes from patenting, and subsequent issuance of licenses or dedication of the patent to the public.

The Department regulations specify the machinery for determining (1) what are the ownership rights in the invention, and (2) whether or not an application for a patent should be filed.

4. WHAT AN "INVENTION" IS

Any process, art or method, machine, manufacture, or composition of matter, or improvement thereof may constitute an invention if it has the qualities of:

—novelty
—utility
—invention (in the sense that it would not have been obvious to a person having ordinary skill in the art to which it relates).

All these terms have special meanings under the patent law, and only the Patent Office and, finally, the courts can decide whether a discovery or invention has the requisites of a valid patent. The Department is responsible, however, for making a preliminary determination as to whether an employee inven-

tion "is or may be" patentable for the purpose of Executive Order 10096. If this determination is negative, no further action is required on the invention report, described below.

5. REPORT OF INVENTION

A. *Duty To Report Promptly.* Whenever any employee of the Department makes an invention which may be patentable and bears any relation to his work, or to which Government facilities have in any way contributed, it is his duty to report it promptly in order that determinations as to patentability, ownership of domestic rights and acquisitions of foreign rights may be made.

The right to patent an invention is lost if more than one year elapses after the invention is published or in public use and before a patent application is filed in the Patent Office. As it takes considerable time after an invention is reported to make the necessary determinations and to prepare and file a formal patent application, if that is decided to be necessary, it is important that inventions should be reported promptly and that the report should give full information concerning any publication or public use.

B. *Employees Required To Report.* All employees of the Department are subject to the reporting requirements; including commissioned and other officers, and including part-time employees and consultants.

C. *To Whom Report Is Made.* The report should be made through administrative channels to the head of the operating agency or, by an employee of the Office of the Secretary to the Director of Administration (Sec. 7.1, Regulations).

D. *Form of Report.* Exhibit 1 (attached) should be followed for the "Report of Invention." It will not always be necessary to prepare the report in complete detail since it may be apparent on the basis of a preliminary and less detailed report, that the supposed invention lacks the novelty or utility required for patentability, or that circumstances permit a disposition of the report without a complete invention description.

E. *Confidentiality of Report.* Invention reports required of employees are confidential and may be disclosed only for official purposes or with the consent of the inventor (Sec. 6.4, Regulations).

6. DETERMINING OWNERSHIP OF EMPLOYEE INVENTIONS

A. *Rules Governing Determination.* The rules governing determination of rights in invention coming under the provisions of the Executive Order 10096 are briefly summarized below:

(1) Subject to the exceptions mentioned below, the Government is entitled to the ownership of any employee's invention in any case where:

(a) The invention was made during working hours; *or*

(b) was made with a contribution of Government facilities, equipment, materials, funds, or information, or of official time or services of other Government employees; *or*

(c) was directly related to the employee's duties or made in consequence to such duties.

(2) Even though the foregoing conditions exist, however, the title to an invention will be left in the employee, subject to a royalty-free license for the Government to use it, if the Department determines (subject to approval by the Chairman of the Government Patents Board) that either of the following conditions exist:

(a) that the Government's contribution has been insufficient equitably to justify assignment of all rights; *or*

(b) that the Government has insufficient interest in the invention to require complete assignment.

(3) The Executive Order also provides certain presumptive guides for applying these rules, including the consideration, for example, of such factors as whether the inventor was employed or assigned to make improvements, or to do research or development work, or to supervise such work or act in a liaison capacity.

(4) In other cases where the conditions of (1) above do not exist, all rights in the invention are left in the employee.

Recommendations as to the acquisition of foreign rights are also required.

B. *Procedure for Department Determination.* The determination will be made for the Department initially by the head of the employee's office or operating agency, who will forward the determination and the Report on Invention to the Department Patents Officer for review.

This determination will constitute the decision of the Department unless the Department Patents Officer upon review has questions concerning the determination which remain unresolved after consultation with the originating unit. Such questions will be submitted by the Department Patents Officer to the Department Patents Board which shall either affirm or reverse the determination, or return it to the head of the office or operating agency for further action (Sec. 7.6, Regulations).

If the Board proposes to make or affirm a determination requiring the invention to be assigned to the Government, it may in its discretion afford the employee the opportunity of a hearing (Sec. 7.6, Regulations).

C. *Notice of Determination.* The employee (unless he waives the right to notice) will be notified in writing of the Department's determination by the head of his operating agency or, if an employee of the Office of the Secretary, by the Director of Administration, unless the determination is made by the Department Patents Board, in which case he will be notified by the Department Patents Officer (Sec. 7.7, Regulations).

D. *Right to Appeal.* An employee aggrieved by a determination of the Department has the right to file a written appeal with the Chairman of the Government Patents Board within thirty days after receiving the written notice of the Department's determination (Sec. 7.8, Regulations). Four copies of the appeal should be sent to the Chairman of the Government Patents Board, Department of Commerce, Washington, D.C., and one copy to the Department Patents Officer.

7. Prosecuting a Patent Application Without Fee

Whether or not the Government has or acquires ownership rights in the invention, it is possible for a Department employee to apply for a patent, without cost to him for Patent Office fees, if the Secretary (or his designee for this purpose) certifies that the invention is used or is likely to be used in the public interest, 35 U.S.C. 266. The employee may utilize the attached invention report form for this purpose of requesting such certification.

8. Relation to Incentive Awards Program

The requirements of the Department patent regulations are independent of the Department's Incentive Awards Program. However, an invention reported under the regulations is eligible for consideration under the Department's Incentive Awards Program.

General Administration Manual Guide HEW-1 (10/19/56). Exhibit 1

REPORT OF INVENTION—OUTLINE FOR USE BY EMPLOYEE

Department of Health, Education, and Welfare

REPORT OF INVENTION

Date:

Inventor: (Name of inventor or inventors)

Employee status: (Indicate whether a regular or special type of employee, and name of operating agency and unit where presently employed; e.g., "Employee, Public Health Service, National Cancer Institute.")

Invention: (Indicate short descriptive name)

Relation to official duties—Contribution of Government facilities, etc.: This should include a statement of the inventor's status and employment from the time of the conception of the invention to its reduction to practice or disclosure, and facts as to the relation of his work on the invention to his official duties and working hours and to the use of Government facilities, material, services, or information.)

Co-inventors: (Indicate the names, status and contributions of possible co-inventors)

Invention Description (Abstract): (This should consist of a clear and concise summary of the invention, emphasizing its novel features and probable usefulness, in 100 words or less of simple language (nontechnical where possible), including:

(a) What it is or to what it relates;

(b) Its construction, if a machine, apparatus, device, or article;

(c) Its identity, if a chemical compound, or its ingredients, if a mixture, including the production thereof if not obvious;

(d) The procedure involved, if a process;
(e) Its manner of operation (how it works), if a machine, apparatus, device, or article;
(f) What it accomplishes or is intended to accomplish over the known prior art;
(g) The modifications or species disclosed.

More detailed descriptive material may be attached but is generally not needed except in connection with an actual patent application if one is made.)

Publication and related factors: (Brief statement as to any prior publication or disclosure, and of evidence available as to conception of the invention, disclosure, and reduction to practice.)

Advisability of patenting: (Inventor's remarks, if any, as to advisability in the public interest of patent protection for this particular invention. State briefly the pertinent considerations. Indicate also the countries, if any, in which patent protection would be desirable, and why.)

Interest of inventor: The undersigned has made what he believes may be a patentable invention. This report is submitted pursuant to Executive Order 10096 and Department regulations in order that formal determination may be made as to the Government's rights and interests therein and as to whether domestic or foreign patent protection thereof should be sought.

(It will be helpful if under this heading the inventor indicates (1) whether he agrees to abide by the results of such determination and to execute such assignments, licenses and applications for patent (without cost to the inventor) with respect to such invention as may be required pursuant to such determination, (2) whether he claims specific rights in the invention and, if so, the nature and extent of his claim, (3) whether he wishes to file a patent application under 35 U.S.C. 266, (4) whether he wishes the invention to be dedicated to the public.)

_____
(Signature of inventor)

Residence address:

Office address:

APPENDIX D

JANUARY 22, 1958.

EXPLANATORY STATEMENT CONCERNING THE PATENT POLICY OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE WITH RESPECT TO CONTRACT RESEARCH AND RESEARCH GRANTS [1]

The policy of the Department of Health, Education, and Welfare with respect to inventions arising from research conducted with the aid of grants or in the performance of contracts for research is set forth in regulations of the Department (45 C.F.R., pts. 6–8). These were recently amended to provide more explicitly for contract research and to authorize special alternatives for industrial contracts for the cancer chemotherapy research program. Specific authority to contract for research is comparatively new for this Department, and applies to relatively few programs. Research grant authority is of long standing, and applies to a greater number of programs, including most of those in which there is authority to contract for research.

The distinction between contracts and grants for research is, roughly speaking, a distinction between a procurement or purchase and assistance or support. Under the research contract authority research for which the Government is to pay is undertaken by an institution pursuant to contractual obligations and in accordance with specifications by the Government. A research grant, on the other hand, is made in support of research activities or projects proposed by an applicant institution. The patent policy has been framed in the light of these distinctions as well as with regard to the basic policy objectives of all research programs of the Department.

The regulations of the Department are controlling on the various constituent agencies of the Department (such as the Public Health Service) in the award of grants and in the negotiation of contracts and also in determining the dis-

[1] This statement approved by the Department Patents Board on Jan. 22, 1958, for use with the Department regulations and informally as appropriate.

position to be made of rights in inventions in accordance with the terms of such awards or contracts.

TERMS AND CONDITIONS

The regulations provide as a standard condition that there be reserved to the head of the constituent organization entering into the contract the right to determine the disposition of inventions which are first conceived or reduced to practice in the course of the performance of the contract (Regs. 8.6). This standard applies to all industrial contract research, although certain alternatives are available in the cancer chemotherapy program (Regs. 8.7).

A similar standard applies to research grants, but a broader alternative is also afforded. Under this the determination of rights in and the disposition of inventions may be left wholly to the grantee institution to be made in accordance with its own established policies and procedures. This alternative is available when the head of the organization making the grant has determined that the policies of the grantee institution (with such modifications as may be agreed to and are specified in the grant) are such as to assure that inventions will be made available without unreasonable restrictions or excessive royalties (Regs. 8.1(b)).

When the policies and procedures of a nonprofit institution have been thus accepted for grant purposes, research contracts with the same institution may also provide, as an alternative to a reservation of the right of determination to the head of the constituent organization, that inventions shall be left to the institution for disposition in accordance with its accepted policies, with such stipulations in the contract as may be deemed necessary in the public interest (Regs. 8.6(b)).

POLICY OBJECTIVES—DISPOSITION OF RIGHTS

The underlying purpose of the research programs of this Department is the advancement of knowledge and development of techniques for use as broadly as possible for the public health and welfare. It is the position of the Department that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public (Regs. 8.0(b)).

Accordingly, when under either a grant or contract the right of determination is reserved to the Government (i.e., to the head of the operating agency in the department which is responsible for the grant or contract), it is subject in its exercise to the following controls:

1. Dedication to the public by publication (in contrast to patenting) is generally to be preferred (Regs. 6.2).

2. Patenting of the invention by the Department is to be sought only when circumstances indicate that this is desirable in the public interest (Regs. 6.2).

3. Licenses under patents administered by the Department are to be issued on a royalty-free, nonexclusive basis and, except in unusual cases such as those where controls of a harmful product may be deemed necessary, are to be available to all applicants unconditionally (Regs. 6.3).

The fact that there is reserved to the Government the right of determining the disposition of an invention does not mean that assignment of rights to the Government will necessarily be required.

In the case of an invention arising under either a grant or contract, if the grantee or contracting organization proposes to make a disposition of the invention which it believes to be in the public interest, the head of the organization may concur in the proposal provided he finds that under it the invention will either be effectively dedicated to the public or (if patented) will be generally available for royalty-free and nonexclusive licensing (Regs. 8.2(a), 8.6). This is in fact the type of determination which is usually made when the institution making the proposal has a patent policy with objectives similar to those of the Department.

Additionally, the head of the constituent organization may approve a proposal for the assignment of an invention for a limited period (which could even be for the life of the patent) to a competent organization for development purposes if he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices (Regs. 8.2(b)).

Such determinations are made on the basis of all the circumstances in the individual case and a judgment as to how the public interest will be best served.

LICENSE TO THE GOVERNMENT

In any case when an invention whose disposition is subject to determination by the Government is left to the grantee or contracting institution, there must be reserved to the Government (if a patent is sought) a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

APPENDIX E

List of Government-owned patents on inventions arising from activities of the Department of Health, Education, and Welfare (or predecessor agencies) [1]

[E=employee; G=grantee; C=contractor; F=fellow]

	Number and date of patent	Inventor-relationships	Title of invention	Licenses or disposition
1	1,930,972 [2] (1934)	Small (PHS-E)	Morphine Derivatives, etc	
2	2,058,521 [2] (1936)	do	Ethers of Morphine and its Dihydrogenated Derivatives, etc.	
3	2,104,058 [2] (1938)	do	Ethers of Morphine and Dihydromorphine and their N-oxides.	
4	2,132,721 (1939)	Hudson and Richtmyer (PHS-E).	Production of D-ribose from Calcium D-altronate.	
5	2,178,010 [2] (1939)	Small and Fitch (PHS-E)	Nuclear Substituted Derivatives of the Morphine Series (Metopon).	Extensive conditional licenses—Later dedicated to public use.
6	2,197,885 (1940)	Brodie (St. Elizabeths-E)	Method for Controlling Insect Pests.	Gift to the United States.
7	2,207,338 [2] (1940)	Hudson and Richtmyer (PHS-E).	Production of D-Altronic Acid bred from Sedoheptulose.	
8	2,207,725 [2] (1940) (also 2,257,111).	Elvove (PHS-E)	Removal of Fluorides from Drinking Water.	License and cross-license agreement.
9	2,234,981 [2] (1942)	Rosenthal and Bauer (PHS-E).	Formaldehyde Sulphoxylate Derivatives.	Licenses.
10	2,280,356 [2] (1942)	do	Benzene Sulphonanidyl Compounds.	do.
11	2,370,662 (1945)	Hertz and Sebrell (PHS-E)	Method of Producing Biotin Inactivating Material.	
12	2,371,244 (1945)	Lax (PHS-G)	Device for Recording Blood Vessel Pulsation.	
13	2,491,537 (1949)	Welch (F. & D.-E)	Liquid Injectible Oil Pectin Drug Therapeutic Compositions.	
14	2,518,510 (1950)	do	Stable Injectible Oil Pectin Therapeutic Compositions.	
15	2,531,451 (1950)	Maier (PHS-E)	Water Purification, Etc	do.
16	2,537,960 (1951)	Allen (PHS-E)	Substituted Diaminostilbenes	
17	2,539,388 (1951)	do	Preparation of Aminoindane Compounds.	
18	2,541,056 (1951)	Heftmann (PHS-E)	Screening Method for Blood Glucose.	do.
19	2,553,593 (1951)	Maier (PHS-E)	Regenerating Hydroxyapatites, etc., for Use as Fluoride Absorbent Reagents.	
20	2,557,164 (1951)	Wender (PHS-G)	Isolating Quercitrin from Peanut Hulls.	
21	2,557,987 (1951)	Marshak (PHS-E)	Therapeutic Composition and Method.	
22	2,563,806 (1951)	Allen (PHS-E)	Substituted Bisaminophenyl Ethylene.	
23	2,569,300 (1951)	Fieser and Rajagopalan (PHS-F).	Selective Oxidation of Steroid Alcohols.	
24	2,571,115 (1951)	Davis (PHS-E)	Isolation of Bacterial Mutants.	
25	2,572,864 (1951)	Sumerford and Jensen (PHS-E).	Pine-gum Rosin DDT Insecticide Compositions.	
26	2,572,897 (1951)	Welch (F. & D.-E)	Aureotracin—and Process of Production.	
27	2,594,374 (1952)	do	Streptomycin-polymyxin Bacitracin Composition.	
28	2,601,350 (1952)	do	Hydrolysis of Beta Lactam Linkage by Penicillinase.	

See footnotes at end of table, p. 88.

APPENDIX E—Continued

[E=employee; G=grantee; C=contractor; F=fellow]

	Number and date of patent	Inventor-relationships	Title of invention	Licenses or disposition
29	2,602,252 (1952)	Shinn (PHS–E)	Exhibiting Device	Licensed.
30	2,603,583 (1952)	Welch (F. & D.–E)	Pectin Penicillin Preparation and Process for Production.	
31	2,604,474 (1952)	Elderfield & Werble (PHS–E).	"Primaquine"	do.
32	2,611,368 (1952)	Pecora (PHS–E)	German Silver Electro-Cardiograph Contact Electrode.	
33	2,616,828 (1952)	Levintow and Greenstein (PHS–E).	Enzymatic Resolution of Amino Acids.	
34	2,649,727 (1953)	Snow and Staub (PHS–E)	Chemical Fume Hood	
35	2,651,236 (1953)	Kabler (PHS–E)	Thermal Expansion Device	
36	2,653,160 (1953)	Doak and Freedman (PHS–E).	Preparation of Organometallic Compounds in Organic Solvents.	
37	2,658,021 (1953)	Earle and Sanford (PHS–E)	Tissue Culture Procedures	
38	2,684,365 (1954)	Mosettig, Sato, and Katz (PHS–E).	Converting Tomatidine	Dedicated to public (1956).
39	2,796,382 (1957)	Talalay (PHS–E)	Chemical Transformation of Steroids by Means of Bacterial Enzymes.	
40	2,802,391 (1957)	Maier (PHS–E)	Improved Colorimeter	
41	2,858,036 (1958)	Earle and Highhouse (PHS–E).	Culture Flask for use with Plane Surface Subtrate Tissue Culture.	Dedicated to public (1958).
42	2,892,755 (1959)	Portnoy (PHS–E)	Process for Preparing a Serologically Active Fraction of Virulent Treponema Pallidum.	

[1] Also Design Patents 136,449; 136,450; 136,554 (1943) by Parnis. These were for uniforms of the PHS Cadet Nurse Corps, assigned to United States under terms of the contract for their manufacture.
[2] Transferred from Treasury Department.

APPENDIX F[1]

Employee and grantee invention reports received by National Institutes of Health, Public Health Service, 1953–59

Year	Employee	Grantee	Total	Year	Employee	Grantee	Total
1953	8	2	10	1958	11	9	20
1954	8	3	11	1959	8	16	24
1955	3	6	9				
1956	6	12	18	Total	49	54	103
1957	5	6	11				

APPENDIX G

Invention agreements of the Public Health Service with nonprofit institutions[1]

	Institution	Date		Institution	Date
1st	Iowa State	Sept. 14, 1953	12th	Harvard University	Jan. 3, 1955
2d	Northwestern University	Nov. 16, 1953	13th	University of California	May 13, 1955
3d	Cornell University	Dec. 11, 1953	14th	Tufts University	May 27, 1955
4th	Purdue University	Dec. 24, 1953	15th	Massachusetts Institute of Technology.	June 15, 1955
5th	Ohio State University	Feb. 2, 1954	16th	University of Kansas	Aug. 16, 1956
6th	Princeton University	May 5, 1954	17th	California Institute of Technology.	Feb. 21, 1956
7th	University of Illinois	June 17, 1954			
8th	Mount Sinai Hospital New York City.	July 19, 1954	18th	Florida State	June 8, 1956
9th	Michigan State	Oct. 13, 1954	19th	Washington State University.	Oct. 14, 1958
10th	University of Washington	do.			
11th	University of Minnesota	Nov. 3, 1954			

[1] Agreements with 7 other institutions were pending as of Dec. 31, 1959.

APPENDIX H

SAMPLE LETTER OF AGREEMENT WITH NONPROFIT INSTITUTION

AUGUST 11, 1955.

DR. WILLIAM J. ARGERSINGER, Jr.,
Assistant Dean in Charge of Research Contracts,
University of Kansas, Lawrence, Kans.

DEAR DR. ARGERSINGER: In reply to your letter of October 19, 1954, I am pleased to advise that it has been determined, pursuant to provisions of section 2(b) of Department Order 110-1, "Inventions Resulting from Research Grants," that the ownership and disposition of all domestic rights in inventions arising under Public Health Service grants and awards made to the University of Kansas shall be left for administration by the university.

It has been noted in the review of the materials submitted by you that the policy provides that all results of experimental work, including patents shall be used and controlled so as to produce the greatest benefit to the university and to the public. It has been noted that the University of Kansas Research Foundation acts as the agent of the university in obtaining and administering patents on inventions resulting from research sponsored by or through the university. It has been pointed out that in carrying out its functions in the patent area, the research foundation uses the patent service of Research Corp. of New York under signed memorandums of agreement executed for specific inventions. The overall patenting and licensing practices of Research Corp. have been found acceptable to the Public Health Service. I have also taken cognizance of the fact that the University of Kansas has a policy of dedication to the public through publication, reserving to itself the right to publish all material of fundamental value to science and technology.

This determination is subject to the following understandings and conditions, and upon acceptance will apply to inventions under current grants and awards and to those made while it remains in effect:

(1) The university will make its determinations in accordance with its formally adopted patent policy, as supplemented by your letters of March 30, 1955, and July 1, 1955, addressed to the Division of Research Grants, National Institutes of Health, Bethesda, Md.

(2) The university will report to the Public Health Service on each invention which appears to be patentable and which arises under research assisted by grants and awards to the university by the Public Health Service. Such report shall be furnished immediately on the filing of a patent application on any such invention, and the university will furnish to the Public Health Service an annual report showing the disposition of all such inventions.

(3) The university will reserve to the United States in any such patent application and in any patent issued thereunder a nonexclusive, irrevocable, and royalty-free license to make and use, and to sell as provided by law, embodiments of the invention, with power to sublicense, for all governmental purposes.

(4) The university will reserve an option to the Government to file foreign patent applications on any such invention, and will convey to the Government upon demand the rights necessary to enable the Government to prosecute such application and obtain patents in foreign countries, such option to run for 6 months from the date of filing of a patent application in the United States. If the Government either fails (*a*) to exercise this option within the period specified, or (*b*) determines within this period not to exercise its rights to an option, the university may dispose of all foreign rights in the invention, subject to the reservation to the United States of a nonexclusive, irrevocable, royalty-free license to make, use, and sell embodiments of the invention, with power to sublicense, for all governmental purposes.

Please have two copies of this agreement signed by an official authorized to commit the university in the space indicated below and return one copy to the Division of Research Grants, National Institutes of Health, Bethesda, Md., retaining the other for your files.

Sincerely yours,

/s/ ———— ————,
Surgeon General.

UNIVERSITY OF KANSAS,
By /s/ FRANKLIN D. MURPHY.

Date: August 16, 1955.

APPENDIX I (1)

PUBLIC PROPERTY ACKNOWLEDGMENT FORMS USED AT LABORATORY AIDS BRANCH, NATIONAL INSTITUTES OF HEALTH

DIVISION OF RESEARCH SERVICES

LABORATORY AIDS BRANCH

INSTRUMENT SECTION, NIH

PUBLIC PROPERTY ACKNOWLEDGMENT

In consideration of permission from the National Institutes of Health to use the item:

Drawing No. _____ *Apparatus* _____

I agree to respect the premise that this device and/or technique was developed at Government expense for public use in furtherance of the national welfare and acknowledge that all rights thereto remain the property of the Federal Government.

Signature _____
Signature _____
Title _____
Title _____

Name and address of institution where this development will be used

_____
_____
_____
_____

Date: _____

APPENDIX I (2)

DIVISION OF RESEARCH SERVICES

LABORATORY AIDS BRANCH

INSTRUMENT SECTION, NIH

ACKNOWLEDGMENT FORM

I agree to use the following acknowledgment on all advertising for the mentioned item and will submit said brochure to NIH for editorial approval prior to printing.

ACKNOWLEDGMENT

Developed at the Instrument Section, Laboratory Aids Branch, Division of Research Services, National Institute of Health, U.S. Department of Health, Education, and Welfare, Public Health Service, Bethesda, Md.

This _____ is produced based on the design
(Name of apparatus)
of _____.
(Name of designer)

Publication reference: _____

_____

_____

Signed _____

Date: _____

APPENDIX J

TRENDS IN FEDERAL SUPPORT OF MEDICAL RESEARCH, 1940–57

(Tables and charts from the "Advancement of Medical Research and Education Through the Department of Health, Education, and Welfare, Final Report of the Secretary's Consultants on Medical Research and Education, June 27, 1958," available from Superintendent of Documents, U.S. Government Printing Office)

TABLE 7.—*Total and Federal medical research expenditures, 1940–57*

[In millions]

Year	Total national medical research	Federal medical research	Federal as percent of total
1940	$45	$3	7
1947	88	28	32
1952	148	73	49
1953	203	84	41
1954	225	97	43
1955	240	107	45
1956	270	118	44
1957	330	186	56

TABLE 8.—*Medical research expenditures of Federal agencies, 1953 and 1957*

[In millions]

Department	1953		1957	
	Amount	Percent	Amount	Percent
Total	$84	100	$186	100
Health, Education, and Welfare	44	52	138	76
Defense	25	30	23	12
Atomic Energy Commission	10	12	14	7
Veterans' Administration	5	6	11	5

CHART D

SUPPORT OF MEDICAL RESEARCH BY FEDERAL AGENCIES— DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE BECOMING MORE IMPORTANT

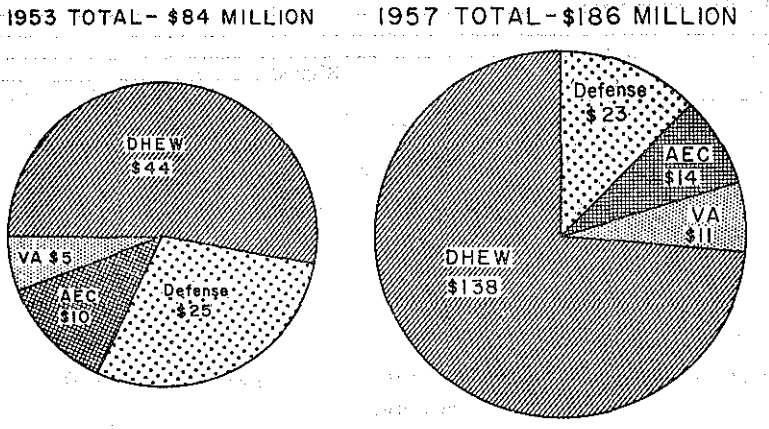

CHART E

MEDICAL RESEARCH EXPENDITURES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FISCAL YEAR 1958

National Institutes of Health most significant

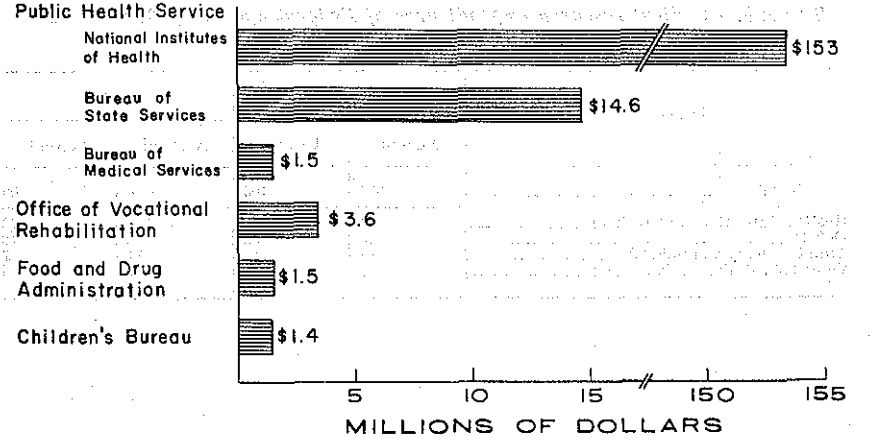

CHART F

GROWTH OF NATIONAL INSTITUTES OF HEALTH APPROPRIATIONS

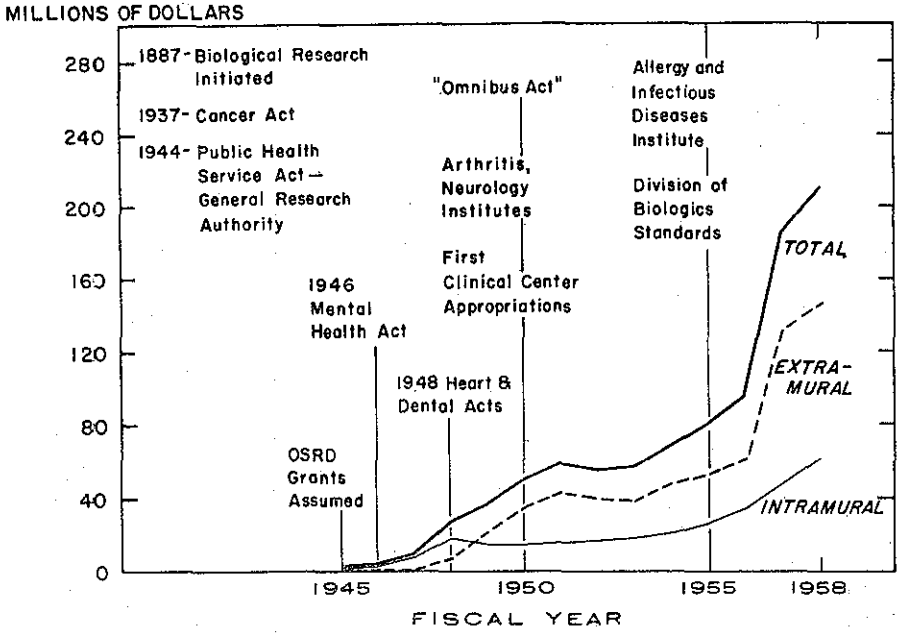

TABLE 18.—*Evolution of NIH appropriations, fiscal years 1955–58*

[In millions]

Item	1955	1956	1957	1958
Total	$81.3	$98.4	$183.0	$211.2
Research grants	33.9	38.3	89.7	97.7
Training and fellowships	13.6	17.3	33.4	39.4
Other extramural [1]	6.8	7.6	10.3	10.3
Subtotal extramural	54.3	63.2	133.4	147.4
Direct research	23.7	29.5	35.9	41.5
Chemotherapy contracts		1.3	4.7	12.3
Other [2]	3.3	4.4	9.0	10.0
Subtotal intramural	27.0	35.2	49.6	63.8

[1] Disease control and field investigations.
[2] Review and approval of grants, professional and technical assistance, and administration.