A Short History Of Licensing

By Joseph K. Andonian

My career in licensing began in 1951 and overlaps the history of LES. I participated in at least one of the early discussions that gave birth to LES. It took place at a PLI seminar in New York City on the handling of surplus technology about 1960. The first president of LES (Dan Stice) and the first editor of les Nouvelles (Jack Ott's predecessor) took part in that meeting.

Since 1941 I have been a participant and an observer in the practical and business aspects of creating, acquiring and disposing of intellectual assets including but not limited to what is commonly referred to as licensing. I have personally observed and participated in thousands of licensing transactions and the related activities of the business community in the area of intellectual property with a particular focus on the automobile, military and pharmaceutical industries. From my perspective licensing is a tool for commercializing intellectual property per se. Its use and significance depends entirely on how much value is attached by the community at large to the intellectual subject matter involved, legally, morally and economically. What I have rightly or wrongly learned beyond the nuts and bolts of licensing per se throughout my 66 year long career may be of interest to present day licensing professionals.

The Automobile Industry

Let's start with the automobile industry. I grew up in the very center of the domestic automobile industry in Pontiac, Michigan, between Detroit and Flint where General Motors (GM), Ford and Chrysler are largely located, less so now than they were at the beginning of my career. My interest in inventive activity began while being employed on and off by General Motors (GM) and a student at General Motors Institute during the period from 1942 to 1951. My early thinking was influenced by reading material about inventors distributed to employees, largely at the behest of Charles Kettering. Kettering was the inventor of the automobile self-starter and a long time head of General Motors Research. He was also the author of an article published in the Saturday Evening Post entitled "Get Off Route 25," in which he used a traffic analogy to promote the idea that inventions are made from unconventional thinking. He established a policy at GM that promoted internal creativity to the exclusion of outside sources of invention, or a perfect example of what we usually refer to as an 'NIH' or "not invented here" policy. If it wasn't invented by GM, GM was not interested in acquiring rights to it.

For example, an early inventor of automatic transmissions by the name of Oscar H. Banker, a self taught hydraulic engineer who ultimately received a Distinguished Service Award in 1969 from the Automotive Hall of Fame, was unable to demonstrate his invention directly to General Motors Research. Through an arrangement made by his financial backer he opted instead to demonstrate his invention to the Fisher brothers, whose name originally adorned the bodies of all GM passenger cars, i.e., Fisher Body. The Fisher brothers, major stockholders and officers of GM, were sufficiently impressed by the demonstration to write a memo to Kettering asking him to investigate and report back his views on the Banker transmission. Kettering arranged to meet with Banker at the entrance of the GM building in Detroit. When Banker arrived in a car equipped with his automatic transmission, Kettering climbed into the car and asked Banker to drive around the building after which Kettering climbed out of the car without further conversation or examination of the car. That was the last Banker heard from GM. Banker did succeed in having his transmission installed first in double-decker busses operating in New York City and Chicago and later in Ford automobiles. A GM research engineer (actually my brother) told me that Kettering's openly expressed opinion was "if anybody can do it, GM can do it better."

About 1970 a GM patent attorney gave a presentation at an LES Regional Meeting in Dearborn, Michigan, and reported that GM had taken one or two licenses from an outside source in the preceding year and that it avoided taking licenses but licensed its own patents to all comers. GM was obviously not interested in either saving time or money by acquiring rights to inventions by others or in taking advantage of the exclusivity provided by patents on its own inventions. It was generally believed that GM's biggest concern at that time was antitrust scrutiny. With about 50 percent of the domestic automobile market GM had good reason to avoid the charge of monopolizing automotive technology by adding outside technology to its own massive investment in automotive research. GM was spending as much as two billion dollars on research in a single year, some

of its efforts being spent on such non-automotive technology as heart lung machines.

GM did however have other ways of protecting its business from competition. For example, it had franchise agreements with its dealers that effectively prevented its dealers from selling competitors' automobiles. Along with market power associated with exclusive dealerships, it also had a massive investment in product development and production facilities that discouraged all but the richest and most persistent companies from entering the automobile business as significant competitors. Henry J. Kaiser, who gained considerable wealth and fame by building Liberty Ships during WWII, did try to enter the automobile business after the war by taking advantage of a surplus production facility used during the war to build B24 bombers and the insatiable demand for automobiles existing after the war since civilian production of automobiles was stopped during WWII. However, even with competitive automobiles, aptly named "Kaiser" and "Henry J," he eventually closed up shop before he could establish an effective independent dealer organization to compete effectively once his more established competitors could meet the market's demand for automobiles.

Ford had a different history with respect to intellectual property. After the Patent Office refused to grant Henry Ford a patent on his original automobile invention, a vindictive Henry Ford simply ignored or blackballed the patent system. He also considered Wall Street to be his enemy after it failed to lend him the money he needed to buy out his stockholders so he could have a free hand to build his revolutionary, fully integrated River Rouge plant to build automobiles starting from the most basic raw materials to make steel, rubber, glass and plastic. Even after bankrupting some of his dealers to get the money he needed and incurring some large infringement liabilities, Ford did build his plant and sell stubbornly black automobiles.

These intellectual property policies of the two giants in the automobile industry were apparently acceptable in the early history of the automobile business in the U.S. After all, one can't argue with success. Between them GM and Ford dominated the U.S. automobile industry at least until some time after the oil embargo of 1973-74.

The management of intellectual assets is only one factor in carrying out a successful business. The overall legal and physical infrastructure can be and usually are more important considerations. That infrastructure began to change materially for the U.S. automobile industry when the combination of two major events took place, namely the oil embargo and the change in the law which prevented automobile companies from entering into agreements with its dealers that effectively prevented them from selling competitor's automobiles. GM's market research to the contrary notwithstanding, the sudden interest of consumers in small fuel efficient cars and the quick access of foreign automobile manufacturers to GM and Ford dealer outlets for their cars combined to establish and accelerate foreign automobile intrusion into the U.S. market. The domestic industry could not quickly re-engineer their product lines, facilities and, probably most importantly, their management culture to match foreign automakers. My personal experience also demonstrated to me that rigid job descriptions and high cost pay and benefit scales imposed by labor contracts made domestic automobile companies inefficient and limited their ability to compete with lower cost foreign manufacturers.

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Easy access to the U.S. market without intellectual property and legal obstacles provided a foothold that foreign manufacturers have expanded ever since. Low cost access to domestic dealer organizations trained and financed domestically worked for foreign companies but was not available to Kaiser when he needed it to gain a foothold in the U.S. market. GM and Ford also lost the major advantage they had from their geographic location that provided low cost waterway access to the iron mines of Northern Michigan and the steel plants of Gary, Indiana, and Pittsburgh, Pennsylvania. Not only was the low cost iron ore being depleted in Northern Michigan but the U.S. steel industry also found itself unable to compete as effectively with foreign steelmakers, as accurately predicted by the president of U.S. Steel, after President Kennedy "jawboned" the U.S. steel industry to settle a labor strike by increasing wages and benefits without increasing prices. The necessary funds to pay for research and upgrade steel plants technologically were simply no longer available.

The Drug Industry

After graduation from law school in 1951 my attention and employment shifted from automobiles to pharmaceuticals and, to a lesser extent, military and government intellectual activity. Employed as a patent attorney by The Upjohn Company and as a Naval

reservist, I became involved from the beginning in drafting, negotiating and administering agreements relating to intellectual property. Much like the automobile industry, the pharmaceutical industry and the federal government were initially interested in patents primarily for defensive purposes. They obtained patents to preserve their right to use or license the inventions involved but they did not rely on patents to exclude others from practicing the inventions. The government insisted that patents resulting from government-financed research be licensed nonexclusively. The pharmaceutical industry usually settled patent interferences and overlapping patent situations by exchanging nonexclusive royalty free licenses. For a fixed period the five major Midwest pharmaceutical companies, namely Upjohn, Parke-Davis, Searle, Abbott and Lilly, cross-licensed all of their product inventions. I was shocked when I first learned that the asset value of the patents owned by my employer was listed in the financial records of the company as equivalent to the out-of-pocked expenses incurred by the company to obtain the patents. The protection provided by patents was unimportant since (1) competitors could not get equivalent products approved by the FDA without supplying their own safety and efficacy data, and (2) products could be sold under trademarks, doctors routinely prescribed their products by trademark, and pharmacists were legally required to fill the prescriptions by trademark. After the Kefauver investigations on drug pricing in the U.S. Senate in 1960 and the antitrust scrutiny and legislative changes that followed, the legal environment began to change dramatically for the pharmaceutical industry. Generic companies could get their products approved after patents expired by merely showing bioavailability of the same chemical entities whose safety and efficacy was previously established by the inventor organizations. Moreover, when generics were legally available, pharmacists could substitute, and indeed were encouraged or required to substitute generic products for products prescribed by brand name by legal, insurance or formulary requirements. More recently state laws and consumer practices have changed to allow patients to get their U.S. prescriptions filled outside the U.S. where prices on even identical drugs are cheaper primarily due to price fixing by foreign governments in their universal health care programs. Once patents have expired generic drug companies can also sell their drugs for lower prices because (1) they have no discovery or development expenses and (2) they do not have to deliver information to doctors so they can prescribe the products safely and effectively. The costs and risks associated with discovery and development (now claimed to reach one billion dollars for a major new drug) and the delivery of the information to the physician are all incurred by the company that originally held the patent rights for the drugs involved. All a generic company has to do is show bioavailability to the FDA and manufacture and deliver the drugs to wholesalers or drug dispensers. Even if a prescription is written by brand name, a druggist can and usually does fill the prescription with a generic equivalent if available. In contrast to an automobile trademark, a drug trademark has thereby lost much of its asset value.

Actually the drug industry would have had more financial difficulty adjusting to these changes if the tax haven provided by Congress and Puerto Rico for products produced in Puerto Rico was not available. That legislation was passed to make Puerto Rico more attractive for investment generally but the pharmaceutical industry was uniquely situated to take advantage of it largely because transportation expense was not a major concern for the low physical volume of pharmaceutical products. The automobile industry can't and in fact hasn't done so probably because of transportation considerations. China and individual states in the U.S. are fueling their own attractiveness for investment by doing the same thing namely providing tax breaks to attract financial and information investment.

The market for prescription drugs is considerably different than it is for automobiles and most other products. Physicians prescribe drug products most often by brand name. Druggists usually supply the products by either brand name or increasingly generically. Patients usually obtain the products from druggists who are usually paid by an insurance company, by the government, less and less by the patient or more and more by some combination of the foregoing. Unlike the automobile market, if a consumer asks for a Ford, the dealer can't substitute a Toyota. Depending on the circumstances, anyone in the chain may make the decision as to whether a drug is supplied by brand name or generically. In effect this amounts to a reduction or elimination in the protection available from a trademark on a drug and the franchise built up at considerable expense by the trademark owner for its version of the drug and the information delivery service associated with the trademark.

The pharmaceutical industry has an additional public policy burden. It has been subjected to careful scrutiny by those who are sympathetic to the plight of the sick and helpless. They believe normal business interest in profitability or capital formation

is inappropriate for those serving such a vulnerable part of society. The idea that the industry needs to be profitable to obtain capital to establish, maintain and grow its business or pay for its intellectual services somehow escapes their concern. As a result many countries in the world originally provided only manufacturing process protection for new drugs and enacted compulsory licensing laws thereby eliminating exclusivity for new drugs. Although many of those laws have been abandoned in major countries as a result of efforts to harmonize patent laws throughout the world, most major countries have substituted universal health care systems and fixed pricing to accomplish even more control over the drug industry. To date the U.S. has avoided those practices and became and still is the world center for drug research and development primarily because of the absence of price fixing. However growing movements threaten to enact more laws permitting the importation of foreign drugs based on U.S. prescriptions and negotiations for lower prices for drugs paid for by Medicare and Medicaid. Even a universal health care system including price controls is not out of the realm of possibility for the U.S. A recently introduced Senate Bill would even prevent brand name companies from marketing generic versions of their own drugs further diminishing the protection provided by trademarks.

I have had the opportunity to observe firsthand the universal healthcare system in the Soviet Union with particular emphasis on the availability of drugs in that country. Only the elite, or about one percent of the total population, had access to modern drugs. During my career Russians made very few drug discoveries of their own and they produced very few drugs themselves, even though they had bright scientists with the intellectual capacity to do so. Up until at least 1990, they also had a very primitive patent system. Yet the country as a whole has resources, especially human resources, that in many respects match those of the U.S. The controls exercised by the central government over all facets of the drug business were so onerous that there was very little domestic or foreign incentive to do anything in that field. For the present however the U.S. and most of the rest of the world lacks that level of government control.

As long as the cost of generating drug information in the U.S. is paid for by the U.S. consumer in the absence of price controls in the U.S., drug companies can sell their products abroad at the lower prices dictated by foreign laws. Also as a consequence the U.S. pharmaceutical industry is still the world leader in both drug sales and research and development activity. While U.S. automobile companies, even after outsourcing much of their production to low labor cost countries, is losing sales and profitability, U.S. pharmaceutical companies are still prospering, partly due to Puerto Rico tax breaks. In my opinion this prosperity will continue as long as price controls are not enacted for patented products. Even so, there is still considerable evidence through mergers and cut backs in employment and elimination of production and research facilities that the U.S. pharmaceutical industry is already contracting. Bad press, threats of change plus the difficulty of maintaining earnings in the face of the increasing difficulty of maintaining a sufficient number of patented blockbuster products can still affect the industry by making less capital available for investment. Only a realistic appraisal by lawmakers of the intellectual aspects of the business and the necessity of providing an infrastructure that will support such activity will keep the business from floundering. Sure it would be nice if foreign countries bore their share of the information costs of the business and thereby lower prices for U.S. consumers. But absent some means for accomplishing this, U.S. law makers threaten simply to make the U.S. less capable of supporting the kind of discovery and development activity that has taken place up until now. That would be a tragedy if the promise provided by all of the basic discoveries that elucidate the basic nature of biological systems following the discovery of the structure of DNA and elaboration of the human genome. New drug development following such discoveries is going to cost money, lots of it. Somehow, it has to be paid for. Unrealistically some politicians are simultaneously making pharmaceutical research less profitable while clamoring for government funds to do basic research on stem cells from human embryos. The money required to develop and market products resulting from such research is apparently of less concern to the same politicians. Many politicians are also clamoring for research on more fuel efficient cars that can burn less imported oil and save the planet from global warming while at the same time making it more difficult for the U.S. automobile industry to be financially viable. Such schizophrenia among politicians is a luxury our economic system can't afford.

The drug industry's risks and costs are mainly incurred in the process of generating and disseminating information and less in producing and distributing the drugs themselves. The automobile industry's costs are mainly concentrated in the development, production and distribution of automobiles with a less significant but still important investment in generating and dis-

seminating information. As long as the automobile industry has physical control of its products, it can also protect much of its investment in the information involved. That is not as true for pharmaceuticals. If the information relating to safety and efficacy is more freely available, someone else's product can be substituted and thereby profit from the information service most often provided by the drug originator. Obviously that is not true during the period of product patent protection. After that period however the originator no longer controls the product putting a lot of pressure on making a return during the period of patent protection on what can easily amount to a billion dollar initial investment to generate the information for each product. Automobile companies in contrast have considerably more trademark protection. Such protection is already greatly diluted and may even be eliminated for the pharmaceutical industry after patent expiration. Investment on further research or promotion of unpatented drugs is greatly diminished. As long as trademark protection is available automobile companies can still afford to provide service information and marketing support to their dealers and promote their products to the general public.

Many opportunities to develop information about drugs are not undertaken because of the absence or weakness of patent or trademark protection. For example a four million dollar proposal made by a leading cardiologist to follow up 16 animal studies suggesting that ibuprofen may be useful in treating cardiac disease was not undertaken because there would be no assurance of any payback. A related non-steroidal anti-inflammatory drug, namely aspirin, has been available since the late 1800's but its usefulness in the same field has only been discovered recently. Likewise the unsuitability of aspirin for use by children was also only discovered recently. One wonders whether these important discoveries would have been made earlier if there was more incentive to continue research after patents and trademarks have expired. The word "aspirin" was originally a Bayer trademark but has since become generic. In contrast, automobile companies can continue to improve their products because of continued intellectual property protection, not only by patents on the improvements but also by the continued effectiveness of their trademarks.

The October 2006 issue of les Nouvelles emphasizes the importance of exclusivity to assure the development of patented technology generated by government financed research and asks for LES support to maintain the law allowing the government to grant exclusive licenses. (See "Bayh-Dole: Don't Turn the Clock Back" by Birch Bayh.) The importance of exclusivity also applies to technology generated by the pharmaceutical and automobile industries. Intellectual assets are increasingly being recognized as being important if not critical business assets which can themselves be bought and sold due in part at least to organizations like LES. Like it has for the computer industry, unbundling technology from the associated tangible products is helpful in managing intellectual activities but only to the extent that useful legal protection is available to justify the expense.

To assure prosperity and an orderly society in the past it was only necessary in the past that laws and mores be focused on tangible products produced by human effort. During business meetings I would illustrate this built in bias by stating that attendees would feel an obligation to return a pen left at the meeting to its original owner but would soon forget where the best ideas expressed at the meeting came from. We are now advanced to a point in our history requiring that our attention be equally focused on the intangible products of human effort. When a drug company produces and communicates safety and efficacy data on new drugs, this intangible product of its efforts should be accorded just as effective a form of protection as its tangible counterparts. It should not be made available without cost to the generic drug industry or foreign countries and thence to their customers. If such data were tangible like a bushel of corn, it would be regarded as confiscation to take it from the producer without payment. If a drug company paid the cost of disseminating such information to a physician so he can prescribe the product appropriately, a foreign or generic source should not make the profit from the sale of the product. Again if such effort resulted in a tangible product, society has long accepted the idea that the provider of the product should get the reward for its efforts, not someone else who did nothing to deserve it. Admittedly information and knowledge are harder to protect than tangible products. A farmer can do a lot to protect a bushel of corn he produces by simply maintaining physical control over the corn itself. It's harder for the producer to protect his idea or information or the services required to communicate it. But for the pharmaceutical industry at least we can make it more difficult for generic manufacturers and foreign consumers to get the benefit of data generated and communicated at the expense of the discoverer in the originating country.

The health and security of society, not only in the U.S. but also the countries that trade with the U.S.,

must devote more attention through their laws and moral standards to this problem, otherwise such intellectual activity will certainly diminish and devolve into economic chaos. Already unreliable information about medicines is distributed freely while reliable information goes un-rewarded and indeed is unfairly criticized in the media and inhibited by restrictive legislation. Garbage is cheap but good information costs money and is getting harder to recognize, certainly at the consumer level. Compare the ads for so-called natural products with those for prescription drugs. Prescription drug ads directed to the general public are often accompanied by the equivalent of the package insert usually in almost unreadable fine print that only a healthy person can read. Even doctors have a hard time reading and comprehending such information. Ultimately the consumer has to pay the cost of providing such ads. Unless industry can provide good information to those who buy and use their products or services, consumers will not get good value for their money. The more advanced a society becomes, the more critical it is for the society to provide for infrastructure that assures that adequate compensation is paid for producing and communicating good information.

The Role of LES

To remain meaningful, LES must expand its interest in intellectual property beyond the nuts and bolts of licensing to the whole field of intellectual activity and the necessity of providing a legal and moral infrastructure that compensates contributions in the intellectual field. In evaluating intellectual property it must also consider the total environment in which the intellectual property can be used. The expansion of patent protection to include computer programs and business methods are recent examples of what can be done to protect intellectual activity. Weakening of its trademark protection in the U.S. and price fixing abroad prevents the pharmaceutical industry from participating in the economy on a level playing field with the rest of industry with which it must compete for capital resources. Weak patent protection for drugs has been avoided worldwide because of determined effort by those in the patent fraternity who believe in a level playing field in which the pharmaceutical industry must compete for resources. If organizations like LES don't support the same property rights that other industries enjoy, the benefits derived from safe and effective drugs will greatly diminish. Because the U.S. does not now control drug prices, the U.S. leads the world in drug research and effectively finances drug research for the rest of the world largely at the expense of the U.S. consumer. If the whole world paid its share of drug research there would be less overall drug costs because research would take place where the costs are lowest and drug prices would be lower all over the world. Right now the high cost of drug research is due in large part to the combination of carrying out the research at high cost in the U.S. due to strict U.S. drug regulations and the absence of price controls. Thus as matters now stand, the U.S. has been the most feasible place for carrying out drug research. Where we go from here will depend in large part on what organizations like LES do to influence the infrastructure for the activities of those engaged in intellectual activity. We can't rely on an uninformed general public.

Epilogue

Licensing professionals have a vested interest in the overall environment in which intellectual activities are carried out. They must understand the physical limitations of managing such activities and yet the necessity of providing a legal and moral infrastructure to allow such activities to flourish. They must also do everything they can to influence society generally to assure that such activities flourish, especially as intellectual activity becomes a more important part of overall industrial activity.

They must then address the asset value of information and intellectual property in the context of whatever the existing infrastructure justifies at any given time. History teaches that this is more than a mathematical process. For different reasons patents had much less asset value in the early history of both the automobile and pharmaceutical industries than they have today. Trademarks had much more value in the early history of the pharmaceutical industry than they do today. Asset value also varies from the perspective of the individual company involved. If you can protect your investment in intellectual activity physically or legally without patents or trademarks, the asset value of the latter is greatly diminished. If a company is already dominant (as GM once was) in its industry for whatever reason, it consciously or unconsciously attaches less value to any asset that would enhance its dominance and thereby increase its vulnerability to antitrust or public scrutiny.

The most substantial goal I can propose for anyone whose livelihood depends on intellectual activity is do everything you can to make intellectual activity as close to a fungible entity as possible. Separate it from other contributions to human welfare wherever possible and especially from tangible products so it

can be evaluated on its own merits. For example, I believe it is being accomplished in the U.S. for computer software as distinguished from computer hardware and perhaps for business methods. This may be an objective that may never be completely accomplished, but it should be goal. ■