

**In the Supreme Court**

**LCA 8127/15  
LCA 8263/15**

Before: Justice Y. Danziger  
Justice N. Hendel  
Justice U. Shoham

Applicant in LCA 8127/15  
and Respondent in LCA 8263/15: Manufacturers Association of Israel

v.

Respondents in LCA 8127/15  
and Applicants in LCA 8263/15

1. Merck Sharp & Dohme Corp. f/k/a
2. Merck & Co, Inc.

Applications for Leave to Appeal the  
Jerusalem District Court's decision dated  
November 10, 2015 in MApp 5707-11-14

Date of Session: 3 Nissan, 5776 (April 11, 2016)

On behalf of the Applicant  
in LCA 8127/15 and the  
Respondent in LCA 8263/15: Adv. Tal Band; Adv. Yair Ziv

On behalf of the Respondents  
in LCA 8127/15 and the  
Applicants in LCA 8263/15: Adv. Liad Whatstein; Adv. Uri Fruchtman

On behalf of the Attorney General: Adv. Shimrit Golan

**J U D G M E N T**

**Justice N. Hendel:**

1. Israeli law, like the law in other countries, recognizes the protection of patents. Simply put, and perhaps over simplistically, the registration of a patent grants an individual entity ownership, quasi-ownership or at least a bundle of rights with respect to an invention. This law is not new. Patent laws were legislated centuries ago. The innovation of our times is that in this respect, as well, the world has become a global village, meaning that granting a patent in one country may affect the granting of a patent in another country, and *vice-versa*, its revocation in one country may lead to its revocation in another country. This is not merely an economic insight but rather part of substantive patent law.

An additional characteristic of patent law is that it grants legal protection for a

limited period of time. Whatever the rights may be, they are not eternal. The customary patent protection period in Israel and around the world is twenty years (sec. 52 of the Patent Law, 5727-1967 (hereinafter: the Law)). This period is as the period of one generation. However, that is not the final word with respect to all types of inventions. In regard to pharmaceuticals, where registering a patent is not enough, and marketing them requires obtaining a license from the Ministry of Health, it has been established that the twenty-year period may be extended for a certain period of time that shall not exceed five years. This mechanism is known as an "order of extension".

The two points that were mentioned – the patent's international aspect and the possibility of granting an order of extension – meet at the seam between space and time. As we shall see, the extension period that is granted in an order in one country can be dependent upon what occurs in another country. This is a sensitive matter. This meeting-point between time and space is the basis of the ruling in this case. It is for this reason that the Attorney General requested to join the proceeding and express his position.

#### *Previous Proceedings and the Parties' Arguments*

2. Before us are two applications for leave to appeal that address an order extending the period of patents (hereinafter: "extension order"). One application addresses the constitutionality of shortening an extension order after it has been granted, while the other addresses the method of calculating the period of extension in certain circumstances. The applications were filed on the judgment of the Jerusalem District Court in MApp 5407-11-14 (Judge B. Greenberger), which partially granted an appeal on the decision of the Registrar of Patents, Designs and Trademarks, A. Kling (hereinafter: the "Registrar") (Application to change the period of an order of extension for patent no. 110956 (September 18, 2014)). The latter ruled that it is possible to shorten the extension order in the circumstances of the matter and that its period shall be the shorter of those that were being considered. The District Court upheld the ruling regarding the possibility of shortening the order but prescribed a different method of calculation, such that in the circumstances of the matter at hand, the order was extended beyond the period that had been set by the Registrar.

The sequence of events leading up to the Registrar's ruling and the judgment of the court of first instance is as follows: The various rights to Israeli Patent no. 110956, upon which the Ezetrol medical preparation, which reduces high cholesterol levels in the blood, is based, belong to the Respondents in LCA 8127/15, who are the Applicants in LCA 8263/15 (hereinafter, jointly, for the sake of convenience: "Merck"). According to Section 52 of the Law: "The period of a patent shall be twenty years from the application date". Merck's application was filed in 1994 and its patent was due to expire upon the lapse of twenty years, on September 13, 2104 to be precise. In 1998, the Law was amended and the option of granting an extension order was added, subject to the fulfillment of a number of conditions (Patent (Amendment no. 3) Law, 5758-1998) (hereinafter: Amendment 3 of the Law). Merck took advantage of this option and filed an application for an extension order, which was granted in 2005. The extension period was due to expire on June 23, 2017. In 2006, after the order had been granted, the Law was again amended (Patent (Amendment

no. 7) Law, 5766-2006) (hereinafter: Amendment 7 of the Law). Inter alia, it was provided that the extension period provided in an extension order shall be equal to the shortest extension period granted to the patent in certain countries designated in the Law – subject to a number of conditions that will be specified below (see secs. 64I and 64J of the Law).

At the beginning of 2013, the Applicant in LCA 8127/15 and the Respondent in LCA 8263/15 (hereinafter: "The Manufacturers Association"), filed an application to shorten the extension order that had been granted to Merck, based on the argument that such shortening derives from the calculation method that was provided in Amendment 7 of the Law. The Registrar accepted the application and instructed that the period of the order be shortened such that it would expire on January 22, 2016, based on the period of the extension order that had been granted to the patent in the United States. Merck's appeal to the District Court on the shortening itself was denied, however the court ruled that the period of the extension order that had been granted in the United States should not be relied upon, since it was granted after the extension order had already been granted in Israel. Instead, the court instructed that the order remain in effect until October 17, 2016, based on the period of the extension order that had been granted to the patent in Germany. This led to these two applications for leave, in which each of the parties objects to the ruling against it on one of the issues. Merck claims that it was inappropriate to shorten the extension order that it had been granted. The Manufacturers Association emphasizes that the order should be shortened even more – such that it shall expire on January 22, 2016, and not on October 17, 2016.

3. As noted, Merck's arguments are directed against the very shortening of the extension order that it was granted. According to Merck, this is an unconstitutional infringement of its right to property. It is argued that in light of this infringement, Amendment 7 of the Law should be interpreted in such manner that it shall not apply to orders that were granted prior to the amendment taking effect. According to this line of argument, if the proposed interpretation is rejected then the statutory provisions contradict the provisions of the Basic Law: Human Dignity and Liberty. The Manufacturers Association, on its part, relies in this matter on the judgment of the District Court. However, in another matter – that of the period of the extension order that was granted to Merck – it is of the opinion that the court erred. According to the Manufacturers Association, the judgment did not give sufficient attention to the language of the Law, its purpose and the indications that support that it was the legislative intent to provide that the period of the extension order also be examined on the basis of extension orders that were granted in other countries after the order was granted in Israel. Merck, on the other hand, relies in this matter on the rulings of court of first instance.

The Attorney General submitted notice that he would appear in the proceedings by virtue of his authority pursuant to sec. 1 of the Procedure (Appearance of the Attorney General) [New Version] Ordinance. The Attorney General's position was submitted on the matter of the method of calculating the period of the extension order. According to him, and similar to the Manufacturers Association's position, the Registrar was correct in ruling that the period of the extension order could be shortened pursuant to an order that had been subsequently granted in another country.

## *Discussion and Ruling*

The path I shall take in examining the applications will begin with examining the method of calculating the date of expiration of the order, since the specific arrangement at hand, including the details thereof, is the framework of the constitutional discussion. The interpretation of the Law will assist in understanding its purpose and implications, while delimiting Merck's arguments to the boundaries of the concrete case. This foundation will lead to the discussion in the second matter – the constitutionality of shortening an extension order after it has been granted. Consequently, one must first discuss LCA 8127/15, which was filed by the Manufacturers Association, and thereafter discuss LCA 8263/15, which was filed by Merck.

### *The Method of Calculating the Period of the Extension Order*

4. I have decided to address LCA 8127/15 as though leave were granted and an appeal had been filed pursuant thereto, in light of the general legal nature of the issue of the method of calculating the period of the extension that was determined in an order. The matter is relevant to additional patent cases, inasmuch as the same interpretational dispute could also emerge from the present wording of the Law. Merck's argument that a case such as the one before us is not actually expected to occur in the future in the exact same manner, did not go unnoticed. Merck relies on the European law which allegedly prevents this possibility due to uniformity of periods of extension in various countries. However, as we shall see below, the field of patent extensions is dynamic and is subject to frequent legislative changes. This is the case in Israel and in additional countries. Therefore, the fact that the wording of the Law that is in dispute between the parties is still in effect *in Israel* leads to granting leave to appeal. I shall further state that a sufficiently broad picture of the current European law was not presented, and it is not clear that there is *no* possibility that a similar dispute might emerge. In any event, the matter could emerge in one variation or another in Israeli law, and this is a central consideration in granting leave to appeal.

The Manufacturers Association's argument addresses the method by which the period of the extension order should be calculated pursuant to Amendment 7 of the Law. For the purpose of clarifying the foundation of the dispute, we shall briefly describe the calculation mechanism that was provided by the legislature, as per the wording of the Law at the time:

64I. (a) An extension order shall be in effect, subject to the provisions of section 64J, for a period equal to the shorter of the extension periods that were given to a reference patent in the recognized states.

(b) If a license was applied for only in Israel, then the extension order shall be in effect for a period that is equal to the period from the day on which the application for a license was submitted and until the license was given; provided that the

application on the applicant's behalf was submitted and handled in good faith and with due dispatch.

It is evident that the principle rule is that the period of the extension order shall be equal to the period of the extension that was granted to the similar patent (the "Reference Patent") in certain designated states listed in the Law (hereinafter: "Recognized States"). Incidentally, at the time Amendment 7 of the Law was enacted, in 2006, this list, in principle, comprised 21 countries (including countries such as Japan, Luxembourg, Australia and Switzerland), and at present, since Amendment 11 of the Law, in 2014, only six countries are included – The United States, Britain, Germany, Italy, Spain and France (see Schedule One of the Law). The Law further provides that when an extension order is granted in a number of Recognized States, the period of the order shall be that of the shortest extension period that was granted in any of the countries. This last rule changed the legal situation that existed prior to Amendment 7 of the Law, in the framework of which the period of extension in Israel was not linked to the period of the shortest extension that was granted in one of the Recognized States. To complete the picture, sec. 64J of the Law provides three limitations to this calculation mechanism. First, the period of the extension order shall not exceed five years. Second, the protection of the patent shall in any event expire 14 years after the date on which a permit to market medical equipment or preparations that are protected by the patent was granted in one of the Recognized States. Third, the order will in any event expire if the extension order that was granted in one of the Recognized States expired in that state, or if the patent that was registered there was cancelled.

The question disputed by the parties is how one must act when an extension order is granted in any Recognized State after an extension order was granted in Israel, and the period in the Recognized State is shorter than the period of the Israeli order. The Manufacturers Association argues that the rule of "linking" the Israeli order to an order with the shortest period in a Recognized State also applies in such a case, and therefore, the period that is determined in the Israeli order should be shortened. The representative of the Attorney General also supports this position, in the opinion that was filed in this matter. We would note that procedurally speaking, the Law has a mechanism that allows filing an application to cancel or shorten an extension order that has already been granted, *inter alia*, on the grounds for which one can object to the period of an extension order that has not yet been granted (sec. 64K of the Law). This is what occurred in the case at hand. In contrast, Merck argues that after the period of the Israeli order has been determined, it cannot be shortened in light of an extension order subsequently granted in a Recognized State for a period that is shorter than that which was determined in the Israeli order. Each of the parties seeks to base its position on the language of the Law and its purposes. We shall now turn to examining these matters.

5. The language of the Law does not explicitly provide that the period of an extension order that was granted in a Recognized State after the Israeli order was granted is not taken into consideration. The opposite is also not explicitly provided. Both options coincide with the language, and as the parties rightfully emphasized, indications for each of them can be found. For example, it was provided that "An extension order shall remain in effect... for the duration of the period that is equal to

the period of the shortest extension among the periods of extension that *were granted* to the patent in the Recognized States" (sec. 64I(a) – emphasis added). It can be deduced from this that the period is determined in accordance with the extension orders that were granted in the past and not those that shall be granted after the order is granted. On the other hand, the statement "were granted" can be interpreted in the sense that the legislative intent was to take orders that were granted into consideration, regardless of when they were granted. Meaning, once an extension order is granted in a Recognized State – even after an order was granted in Israel – it is an order that has already "been granted", and the Israeli order can be shortened as a result thereof. Furthermore, the section even uses the language "shall remain in effect... for the duration of the period that is equal to the period of the shortest extension among the periods of extension that *were granted* to the patent...". It can be deduced from this that the period of the order is measured at all times – and not necessarily once – vis-à-vis orders that were granted in Recognized States. Through this prism, the language of the Law actually supports the Manufacturers Association's position that the period shall be shortened in accordance with the situation in other Recognized States.

An additional argument by Merck is that sec. 64J(3), which addresses the expiration of the patent in a Recognized State, provides that an extension order that is granted in Israel "shall expire no later than the first date on which the extension period of the reference patent expires in one of the Recognized States...". Had the legislature so desired, it could have worded sec. 64I(a) in a similar manner, so that it would be clear that the extension order is affected by extension orders subsequently granted in other states. On the other hand, the differences in the wording of the Law can be explained by the fact that sec. 64J addresses cases of the expiration of the extension order in Israel, and therefore the wording "no later than the date..." was applied. In contrast, sec. 64I addresses the means of determining the period, and therefore the legislature did not deem it necessary to explicitly state the date the extension order in a Recognized State was granted. As noted, the Law has a mechanism that allows changing the period of the order as per a person's request, and one of the causes is a cause "pursuant to which it is possible... to object to the matter of the period of [the order]". It thus emerges that the period of the order is dynamic and can also change after the order is granted.

It follows, as was also held by the District Court, that the Law's language does not explicitly rule either way. Hence, we move on to its purpose.

6. Purposive interpretation is multifaceted and multihued. The beacon of the Law is composed of many rays that converge to create the beam that illuminates the citizen's path – the path of the law. The light rays originate from different sources: the historical and material background of the amendment to the Law, the objective purpose of the Law and its subjective aspect – the legislature's purpose, as it emerges from the statute's explanatory notes and from the discussions that preceded it, and other sources from which it is possible to learn about the purpose for which the Law was enacted and how it is meant to realize it (see: HCJ 9098/01 *Ganis v. The Ministry of Building and Housing*, IsrSC 59(4) 241, 261 (2004) [<http://versa.cardozo.yu.edu/opinions/ganis-v-ministry-building-and-housing>]). All of the above, including the content of the Law, will also illuminate our way in interpreting Amendment 7 of the Patent Law.

The District Court accepted Merck's argument that shortening the period of an extension order after it had already been determined, compromises the certainty and finality that are required in order for a company that was awarded an extension order to make plans. I am of the opinion that in the circumstances of the case, the analysis cannot end here. Since the certainty consideration was at the focus of the District Court's ruling, I shall somewhat elaborate and explain why I do not accept this position. It is true that when interpreting a statute, the concern of compromising certainty bears weight as an interpretational consideration (AHARON BARAK INTERPRETATION IN LAW – STATUTORY INTERPRETATION, vol. II 583 (1993)). However, this is one interpretational consideration among many that can be of assistance when the language of the law, or other indications, do not explicitly contradict it. In the case at hand, it appears that the legislature did not consider the matter of the certainty of the date of expiration of an extension order to be a primary concern. We have already referred to sec. 64J(3) of the Law, which at the relevant time provided – and in principle continues to provide – that "an extension order shall expire not later than the first date on which the extension period of the reference patent expires in one of the Recognized States". It emerges that the expiration of the order depends, at any given time, on the status of the similar patent in the Recognized States. We also referred to sec. 64K, which allows filing an application to shorten the extension period and in fact, to reexamine it even after the order was granted. The explanatory notes that accompanied this section of the bill, state as follows:

It shall be noted that one may request to cancel an extension order or change its period *even when the cause of action arises after the extension order was granted*, such as in the case in which after the extension order was granted, the period of a parallel patent was extended in a permitting state [a Recognized State], and the extension period in the permitting state is due to end before the expiration of the period of the extension order (sec. 10 of the Patent (Amendment no. 7) (Extension of Period of a Basic Patent) Bill, 5775-2005, Government Bills 187 (emphasis added)).

I will illustrate the matter through an example. But first it should be made clear that the period of the order and the date of its expiration are two separate matters. The legislature emphasized the fact that the period of the extension orders in the various countries, for example three years, will be identical. However, there may be differences as to the date of expiration of the protection of the patent, which could derive, for example, from the difference in the dates when the patent was due to expire to begin with, as a result of filing the application for its registration at different times in various countries. We will now present the example that will clarify what is stated in the explanatory notes that were cited.

Let us assume, theoretically, that an extension order is granted in Israel for a period of three years – from the date of the end of the patent's twenty-year protection

– which was due to expire on December 31, 2017. After the order was granted in Israel, an extension order was granted in England for a period of three years. However, in England the period of patent protection was due to expire, had the extension orders not been granted, a year before the expiration of the protection of the patent registered in Israel. Therefore, the period of the extension in England is due to expire on December 31, 2016. According to the provisions of sec. 64J(3), the granting of the order in England will also lead to the expiration of the order that was granted in Israel on December 31, 2016, even though the English extension order was granted after its Israeli counterpart. Thus, when an order is granted in a Recognized State, the legislature was willing to sacrifice certainty as to the date of expiration of the extension order in order to "link" the date of expiration of the patent's protection in the two countries. Merck is indeed attempting to distinguish between the example that is presented in the explanatory notes, which was illustrated by the English order example, and the case that is the subject of the rulings of the lower court. In the facts of the case before us, it is agreed that according to each of the scenarios, the Israeli order will expire first. The question is when. In the example that was presented above, the English order was due to expire first, and this is the reason the order in Israel was shortened. In response, and as shall be clarified below, it was stated that this is a distinction without a difference. In any event, the example that is presented in the explanatory notes is sufficient to determine, at the very least, that in the eyes of the legislature, the purpose of creating legal certainty with respect to the date upon which the extension order shall expire does not bear conclusive weight. This is in contrast to the position of the District Court which emphasized that purpose.

Furthermore, in the explanatory notes for the Patent (Amendment No. 13) (Extension of Period of Protection) Bill, 5772-2012, Government Bills 682, it was explicitly provided that the amendment is meant, inter alia, to enhance the degree of certainty required by the pharmaceutical companies (see the general part of the bill). The certainty consideration is not a foreign consideration in patent laws, but it does not stand alone. Alongside the emphasis on certainty, the explanatory notes explicitly state that the Registrar must take into consideration events that occurred after the order was granted in order to reexamine the period of the extension. There is even an explicit determination that in circumstances such as those before us, the period of the order should be shortened as per the shortest order that was granted thereafter (*ibid*, sec. 8). This is a statutory amendment that was subsequent to Amendment 7, which addressed other matters and did not in any way alter the controversial wording, but rather only referred to it in the explanatory notes. In any event, the matter is raised not in order to rule on the interpretational question, but rather, at the very least, to cast doubt on the logic that the legislature was of the view that certainty prevails over the need to choose the shortest extension order that was granted in a Recognized State.

The Attorney General's representative added that compared to other laws, patents are characterized by their very nature by a lack of finality and certainty, and referred to various provisions of law which, in the framework of various proceedings, allow discussing the validity of an existing patent based on causes of action pursuant to which it would have been possible to object to the granting of the patent to begin with (see, for example, secs. 73B and 182 of the Law). There is merit to Merck's argument in this regard that these sections are mainly applied when there



should not have been patent protection to begin with, for example, when it is subsequently discovered that the patent owner did not comply with the threshold conditions, and not necessarily in cases in which the cause of action for cancellation was created after the patent was granted. However, it is important to note that in these sections – as in sec. 64K which addresses the application to shorten extension orders – the legislature provided that there is no statute of limitations. This testifies to that fact that in the special context of patent laws, finality and certainty are of less importance, in light of the heavy weight of the opposing public interest. Justice S. Netanyahu elaborated on this in CA 217/86 *Mordechai Schechter v. Avmatz Ltd.*, IsrSC 44(2) 846, 864 (1990).

These all express the policy of the Patent Law, which imprints a stamp of temporariness on the patent and only grants the inventor conditional protection when the invention and the inventor fulfill those conditions which are based on the public's best interest that the invention is indeed patentable and that the patent owner is indeed its owner.

Blocking the option of challenging the patent due to limitation of actions would lead to the outcome that at the end of the period of limitation, the patent would become absolute. This is an outcome that is contrary to the policy and the spirit of the Patent Law... The conclusion that follows from the Patent Law is that the law rejects the approach of expiration of an application to cancel a patent due to limitation of actions, and does not coincide therewith.

This line of argument also emerges from the discussions at the Constitution, Law and Justice Committee (Minutes of the Meeting of the Constitution, Law and Justice Committee, the 16<sup>th</sup> Knesset (October 11, 2005) (hereinafter: the Committee's Minutes)). For example, the Committee Chair, MK M. Eitan said:

The extension order it grants is flexible... If I take the countries that decided, the Registrar takes the smallest, afterwards, another country that extended less joins, and the Registrar reduces... With a reducing system, I take only the countries in which they were approved (*ibid*, page 20).

In other words, the question of adapting the extension order that was granted to orders that were subsequently granted in other countries was raised during the discussions. The discussion addressed the updating of the period of the order, without an explicit reservation being voiced regarding this arrangement due to compromising the certainty or finality of the order. Further on, the Committee Chair was even asked what happens when an additional country is added, and his answer was "until the shortest one" (*ibid*, page 21). The compromising of certainty was not

the focus of the discussion, which concentrated on the issue of compatibility between the expiration date of the order in Israel and the expiration date in other countries, in terms of the relationship between the generic industry, the ethical industry and Israel's status in the global pharmaceutical market. Even a representative on behalf of Pharma – The Association of the Research-Based Pharmaceutical Companies in Israel – agreed that "we prefer to start from the top and go down. We set a number that decreases when there is new information" (*ibid*). Thus, certainty was not even an issue for the representatives of the industry with which Merck associates itself, who were concerned about other matters.

7. Merck argues that the Law has an additional important purpose – to prevent the expiration of an extension order or a patent in a Recognized State when the patent owner would still be protected in Israel. According to Merck, this need for co-termination is the explanation for the legislature's willingness to revoke the period of an extension order when the market opens to competition in one of the Recognized States. However, occasionally this consideration is irrelevant. This is the case in the matter at hand since both according to Merck's calculation method and according to the Manufacturers Association's calculation method, the Israeli order will allegedly expire first, since the cause of expiration in the case at hand does not derive from sec. 64J(3), which addresses the expiration of the patent in another state, but rather from sec. 64I(a). According to Merck, only in the case of co-termination can one justify compromising certainty. Such an explanation is indeed possible, however it has its shortcomings for several reasons.

First, in the explanatory notes to Amendment 7 of the Law, which were cited above, the example of the expiration of the patent in another country is presented only as an example – "such as" – of a cause of action that emerges after the order in Israel was granted and which results in the shortening of the Israeli extension order. "Such as" is indicative of the fact that this is not the only example. There are other examples. In fact, the most conspicuous additional example of secs. 64I and 64J, other than the example that the legislature presented, is a case such as the one before us. Second, even according to Merck's argument, the legislature was willing to compromise certainty for the sake of the purpose of co-termination of a patent in Israel and in another country. Why is it not possible that the legislature viewed other values as justifying compromising certainty? There is no indication in the Law or in the explanatory notes that the consideration of compromising certainty prevails over any other consideration. I would reiterate that the explanatory notes to the later amendment explicitly provide that one of the purposes of the amendment is to create certainty, while concurrently determining that an extension order should also be shortened in a case such as the one before us, even though this is not a case of co-termination. Third, Merck's argument does not offer any positive reference to any purpose that necessarily supports the interpretation that it proposes. What does the basic calculation method derive from? What is the purpose of considering the orders that were granted in other Recognized States, even when according to each of the scenarios the patent will first expire in the State of Israel? Merck did not offer an answer to this question, which has decisive importance in resolving the dispute.

I would incidentally note that the consideration of opening competition in Israel at the time it is opened in a Recognized State is certainly a central consideration that guided the legislature. The majority of the discussions in the

Constitution, Law and Justice Committee prior to Amendment 7 of the Law focus on this international aspect and on the question whether and in what circumstances it is appropriate that a patent be protected in Israel when it has expired in another country – an outcome which would prejudice the ability of the generic industry in Israel to compete with its foreign competitors. It emerges from Merck's statement of claim that this matter also concerned various actors in the international arena, who examined the Israeli arrangement under Amendment 7 of the Law. However, this consideration, as important as it may be, does not indicate the opposite – a desire to avoid opening competition in Israel as a first country. It is indeed possible that the time of expiration in Israel will be first. Had the legislature desired a consistent rule of co-termination, all it had to do was provide that the protection of a patent would always expire along with the expiration of the extension order or the cancellation of the patent in a Recognized State. It did not do so, but rather prescribed a more complicated mechanism. According to Israeli law, an extension order will expire when the patent protection in another Recognized State expires. However, if according to the rules of Israeli law – a patent and extension order – the period of the extension of patent protection has ended, this situation will not be affected by the existence of an extension order that has not yet expired in another Recognized State. *Prima facie*, according to each of the options, and also according to Merck's above interpretation in the case at hand, the situation will be that of expiration in Israel before the other countries. Moreover, the dispute between the parties is fundamentally based on the fact that the U.S. order was granted after the Israeli order. Had the U.S. order been granted earlier, Merck would not have any claim, even though the period of the Israeli order would have been determined in accordance with the period of the U.S. order, and notwithstanding the expiration of the patent in Israel before its expiration in the United States.

8. What, then, is the purpose that should guide the interpretation of sec. 64I(a) of the Law – a purpose that is neither the creating of certainty nor the equating of dates of expiration of the patents in Israel and in another Recognized State? In order to answer this question, we must revisit the various incarnations of the arrangements, examine the purpose of the extension orders and discover why the legislature chose the specific mechanism for calculating the extension period.

A theoretical key to understanding the purpose of the Law is recognizing the uniqueness of the mechanism of calculating the period. The rule for protecting patents is twenty years. Why does the legislature address various extensions and shortenings in the pharmaceutical field? Article B1 of Chapter D of the Law is entitled "Extending the Period of Protection". One can discern two main channels in sec. 64A, the definitions section. The first is the medical channel. There is a definition of a medical preparation, of what constitutes material – the active ingredient in a medical preparation – and stating that a marketing permit is a permit to market medical equipment or a preparation, and the like. The second is the global channel. The section distinguishes between Recognized European States and other Recognized States, refers to the difference between an extension order that is granted in the United States and an order that is granted in Europe, and defines a "reference patent", which is a patent that, inter alia, is registered in another Recognized State and corresponds to the Israeli patent. What is unique to the pharmaceutical field that warrants the option of an extension order? The answer is that marketing pharmaceuticals requires the involvement of an additional entity – the Ministry of

Health. In this field, an examination of the innovation of the invention is not sufficient. An examination of the pharmaceutical's potential benefit or harm is inherently required. Therefore, marketing pharmaceuticals is contingent upon an approval and licensing procedure. The licensing period takes time, and therefore there is a gap between the time of filing the patent application and the time it is made available for consumer use. This gap does not exist or is not significant in other fields, and this is the origin of extension orders.

The extension period is not meant to be determined in an arbitrary manner. Generally, the presumption is that the twenty-year period achieves the public objective of incentivizing inventors. This is the foundation for the basic rule provided in the Law. Thus, changes to the period are also meant to be derived from this objective, and at the very least, should give it significant weight. Obviously, each field has its own unique nature. The rules for the field of practical physics are not the same as for the field of agricultural developments, and neither are the same as for the pharmaceutical field. The arrangements for incentives, the market forces, the extent of global impact and additional characteristics are not necessarily identical. It should be noted that, at present, pharmaceuticals plays a central role in the economy. The industry requires significant investments and creates enormous revenues. This explains the public economic interest as well as the impact on the individual, who may, unfortunately, suffer various diseases that may benefit from these pharmaceuticals. There is a connection between a plain and simple financial business of an impressive scope and a public service at the highest level. The outcome of this mix is that the path to an extension order traverses weighty considerations, and the legislature, in its capacity as regulator, must keep an eye on the situation in Israel and abroad so the period of time will "be in line" with the patent's terms in other countries, while taking global developments into consideration. Before presenting the analysis, I will summarize in stating that the purpose of the extension order is to compensate the pharmaceutical developers in the form of a certain period of time, but not to over-compensate them. Uniformity among countries must be considered, and this consideration, which, as will be explained, prevails over stability and determining a period that is known in advance – although these also play an important role in the entire picture. In fact, the mere granting of an extension order creates an opening for a calculation that is not completely certain but is rather dynamic.

And from the general picture to the statutory development.

9. Until Amendment 3 of the Law, in 1998, anyone who was not the patent owner was forbidden from performing actions for the purpose of licensing a patent-based product in fields in which such licensing was required, until the period of the patent's protection had lapsed. The main field in which licensing is required is the pharmaceutical industry. As a result, one could only begin the licensing procedures – which may take extended periods of time, and even years – after the expiration of the patent upon which the pharmaceutical was based (see the definition of "Utilizing an Invention" in sec. 1 of the Law prior to the amendment). This situation created a problem: pharmaceutical companies in the "generic industry" – that primarily engages in the manufacturing of pharmaceuticals that utilize existing patents – could not initiate the actions necessary to obtain a license for their products until the relevant patent had expired. Consequently, the approval of generic pharmaceuticals

was delayed for an extended period. Concurrently, in other countries, it was possible to initiate the actions necessary for licensing of the competing pharmaceuticals during the period of the patent's protection. This created a situation in which one day after the patent expired, companies domiciled in one of those countries could file a licensing application, while the Israeli companies could only begin to take the required actions. This situation adversely affected Israeli manufacturers both in the Israeli market and in the export market. Amendment 3 of the Law was intended to allow the use of the patent during the period of its protection, subject to certain conditions, for the purpose of obtaining a marketing license – as opposed to actually marketing – from the Ministry of Health (see sec. (3) of the definition of "Utilizing an Invention" in sec. 1 of the current Law, along with sec. 54A; LCA 2826/04 *Patents Registrar v. Recordati Ireland Limited*, IsrSC 59(2) 85, 87-88 (October 28, 2004) (hereinafter: the *Recordati* case); AMIR FRIEDMAN, PATENTS – LAW, CASE LAW AND COMPARATIVE LAW 123-145, 688, 751-752 (2001) (Hebrew) (hereinafter: FRIEDMAN).

This amendment indeed solved the difficulties of the generic pharmaceutical manufacturing companies, but concurrently created a problem in terms of the patent protection granted to companies that primarily engage in research and development of new pharmaceuticals for the sake of registering patents (hereinafter: the ethical companies). According to the law prior to Amendment 3, these companies actually benefited from an additional period of protection for their registered patents, due to the period of time that was required for the generic companies to receive the Ministry of Health license. This period of time was not perceived as an unearned benefit to the ethical companies, inasmuch as they were themselves required to obtain a Ministry of Health license before they began marketing their pharmaceuticals, which meant that a period of time lapsed between registering the patent and marketing the pharmaceuticals. After the Law was amended, the period of time required for licensing the generic pharmaceuticals was significantly shortened, while the ethical companies still needed an extended period of time until they could begin to market their patent-based pharmaceuticals. In order to reinstate the equilibrium that existed before the amendment of the Law and to prevent harm to the ethical companies, an extension orders arrangement was introduced, similar to those of other countries around the world.

The combination of the possibility of initiating actions towards licensing a patent even before its expiration, along with the possibility of extending the period of the patent's protection beyond twenty years, was meant to address the difficulties of both the ethical and generic industries. On the one hand, the ethical industry was granted an additional period of protection, meant to compensate it for the "lost years". On the other hand, the Israeli generic industry was able to compete with its foreign colleagues, and like them, it could file an application for licensing a generic pharmaceutical immediately after the expiration of the patent (see secs. 54A, 64A-64P of the Law; the Patent (Amendment No. 3) Bill, 5758-1997, Government Bills 2651 (hereinafter: the Government Bill); the Patent (Amendment No. 4) Bill, 5758-1997, Bills 2664 (hereinafter: the Committee Bill); FRIEDMAN, pp. 135-136).

That is the background that leads us to the next stage – the method of calculating the period of the extension. If the objective is to compensate the ethical companies for the loss of the period of protection that was taken from them, then that

is the period of time that should constitute the basis for calculating the period of the extension order. Indeed, the mechanism that was provided in the Law is directed towards that objective. Section 64I(b) refers to a situation in which licensing was requested only in Israel. In this situation, the extension is for the period of time that is equal to the period between filing a license application for the pharmaceutical and its approval – subject to everything being performed with due dispatch. Section 64I(a), as worded at the time, referred to a situation in which licensing was also requested in another Recognized State, and provided that the period of the order shall be the same as the period of the order that was granted in the other state. The assumption is that the extension period is also, to some degree, determined in the Recognized States based on the period of time between the registration of the patent and the receipt of the marketing permit. See, for example, the definition of an "Extension Order on a Reference Patent" in sec. 64A of the current wording of the Law. According to this section, the foreign extension order, pursuant to which the period of the extension in Israel is determined, should be based, inter alia, "in accordance with the term of review for the purpose of providing the first marketing license by the authority accredited to provide marketing licenses" in the United States, or on "the time passed since the filing date for the reference patent and up to the granting date of the first marketing license" in a Recognized European State.

We now reach the heart of the matter: The legislature decided that the period between the application to register the patent and the approval to market it, or the extension period that was granted in a Recognized State based on this figure, properly compensate the patent owner. It should be noted that in this context there is a certain difference between the explanatory notes of the two bills that led to Amendment 3 of the Law – the wording of which is identical, and similar wording was eventually adopted in Amendment 3. The government bill explains that the compensation is for the period of the "actual protection" that the patent owner lost due to the amendment of the Law. The assumption is that the period of the extension order is longer than such period, and therefore the compensation is even more than appropriate:

One cannot determine in advance how much time the licensing procedure of a generic product will take. One can also not foresee how much time will be needed until the patent owner will receive licensing in the State of Israel, although there is no doubt that the period that will be required for the patent owner will always be longer than the period that will be required for licensing the generic product.

The Committee has found that the period that has elapsed since the patent owner obtained the licensing from the Israeli Ministry of Health will be an appropriate period for compensating for the fact that a generic company will be able to enter the market immediately upon the expiration of the patent.

This period will be known when the patent owner submits its application to extend the period of the

patent. This extension will always grant the patent owner a longer period of compensation than the period of the *de-facto* protection that it “will lose” as a result of the amendment of the law (The Government Bill, sec. 3).

Thus, the extension order's objective is to compensate the patent owner for the period of the *de-facto* protection that it lost as a result of the amendment of the Law. The duration of the extension considers the period of time until the patent owner – in Israel or in another state in which an extension order was granted – obtained the license, which is longer than the period of time the patent owner lost. In contrast, the Constitution, Law and Justice Committee's bill noted that the compensation is for the period of time during which the patent was registered but the Ministry of Health's marketing approval had not yet been granted, and therefore, the period of the extension is identical to this period (see the Committee Bill, page 148). In any event, granting the patent owner appropriate compensation is a central objective that the legislature sought to achieve. Even in the current framework, Merck's argument is not directed against the duration of the order that was granted in the United States, in and of itself. No argument was raised that the duration of the period is what infringes its property, but rather only that the order was granted after the Israeli order had been granted. Therefore, for the purpose of the continuation of the discussion, we can establish the following axiom – which was not challenged in any way by either of the parties: A period of protection that is based on an extension order that was granted in a Recognized State (which takes into consideration the period of time that is required for the patent owner to license the pharmaceutical), constitutes appropriate compensation for the patent owner for the period it "lost", either as a result of Amendment 3 of the Law, or as a result of the need for licensing.

After Amendment 3 of the Law, the question arose as to how to calculate the period of an extension order when a number of extension orders have been granted in Recognized States. The interpretation that was given to the Law in the Deputy Registrar's decision in Application to Extend a Period of Protection for Patents no. 84601, 105264, 79336 (July 23, 2003) was that the patent owner may choose a specific state, and the period of extension and the rules of expiration of the patent would be in reference to that state. Amendment 7 of the Law, which explicitly clarified that the Patents Registrar must seek the state in which the extension period that was granted was the shortest, was amended, inter alia, following this decision of the Patents Registrar. The explanatory notes of the Law do not include any explicit reference to choosing this arrangement, however it can be understood in light of the purpose that Amendment 3 was meant to realize. It was possible to amend the Law in the spirit of the Deputy Registrar's decision, or to prescribe a different rule, such as linking the period of the extension order in Israel to the order that was granted first among the Recognized States. Why, then, did the legislature nevertheless chose to follow the state that granted the shortest period of time? It should be noted that the guiding rule that was presented was that the calculation mechanism provided in sec. 64I(a) grants appropriate compensation for the patent owner. Hence, there are grounds for finding that the legislature was of the opinion that there is no flaw in choosing the shortest extension order granted in one of the Recognized States. In any event, and what is the important is that the legislature provided that compensation that is calculated in accordance with the state in which the extension is shortest is

appropriate and realizes the purpose of the Law.

10. Similar conclusions emerge from the deliberations of the Constitution, Law and Justice Committee that preceded Amendment 7 of the Law. The vast majority of the deliberations addressed the co-termination consideration and not the question of the duration of the extension period in cases in which the patent protection expires in Israel before other states. However, there was some reference to this issue as well. At the beginning of the discussion, the background of Amendment 3 of the Law was clarified. As stated by the Committee Chair, MK Eitan: "What interests me is that there will be effective protection for a certain period of time during which I will be able to exhaust the patent". Later in the discussion, the Ministry of Justice representative stated that "in order to reach short periods, we decided to base the period in Israel on the periods abroad". Afterwards, the Committee Chair clarified the situation: "Almost 20 years have passed. I ask the Patents Registrar to give me 5 more years. He sees what is happening in a variety of states, you said. He takes the state in which the patent will expire in the shortest period of time after the lapse of the 20 years..." (Minutes of the Committee, at p. 7). Meaning, the objective is to compensate the patent owner for a certain period of time, and the assumption is that this is realized even by the shortest period of time for which an extension order was granted in another state. Of course, appropriate weight is to be given to the Committee's deliberations. While they do not establish the purpose of the Law, together with the other components of the analysis, one cannot say that they do not bear any weight. It is appropriate here to mention that according to the Law, the purpose of compensating the patent owner also retreats before the co-termination consideration. This is in light of the importance that the legislature attributed to the ability of the Israeli generic industry to compete with foreign companies. However, this purpose, as mentioned, is not directly relevant to the interpretive question we are currently addressing in regard to the date of expiration of the order in a situation in which, in any event, it first expires in Israel.

11. An additional, important component of purposive interpretation, alongside the language of the Law, the various arrangements therein, the explanatory notes and the statements made in the Knesset committees, is the objective purpose of the Law. Through this perspective, one must not forget that at issue is not only a competition between the ethical companies and the generic companies. The public is also part of the story. From the public perspective, the tension inherent in the patent laws is between the interest to the free use of an invention for the benefit of the public, and the desire to provide incentives for development and invention by way of the Law's protection against the copying of the patent:

The conflicting considerations and interests that underlie the patent law system are well reflected in the pharmaceutical arena. On the one hand, the pharmaceutical companies invest extensive funds and significant human resources in developing new pharmaceuticals, and expect to receive proprietary protection for their inventions, which are achieved through immense investment. Granting proprietary protection for an invention encourages developing new pharmaceuticals and



completing the development of existing pharmaceuticals. On the other hand, there is the interest of freedom of competition and occupation of the public and the competitors, which encourages generic pharmaceutical companies to manufacture competing pharmaceuticals at affordable prices that are significantly less expensive than the price of the patent-protected pharmaceuticals. Promoting the interest of the generic companies to distribute competitive pharmaceuticals promotes not only the economic benefit of these companies, but also the interest of the consumer, by significantly reducing the prices of pharmaceuticals in the market (LCA 6025/05 *Merck & Co Inc. v. Teva Pharmaceutical Industries Ltd.*, para. 21 (May 19, 2011), *per* Justice A. Procaccia (hereinafter: the *Merck* case).

It is doubtful whether the public interest in encouraging research and development is prejudiced by adopting the interpretation of the Manufacturers Association and the Attorney General. If sufficient incentive existed prior to Amendment 3 of the Law, the legislature was of the opinion that such incentive was not prejudiced as a result of Amendments 3 and 7, in light of the compensation that is granted to the patent owners. This is also the case if we consider the period of the shortest extension granted in a Recognized State. Reality and the development of the industry since the amendment of the Law do not contradict this position. On the other hand, if the patent owners are over-protected, beyond what is necessary to incentivize them, such protection will certainly be at the expense of the entire public, since the price of the pharmaceuticals significantly declines after the market opens to competition. It emerges that the public interest supports avoiding granting compensation that exceeds that which is necessary to maintain the incentive that the ethical companies enjoyed prior to the amendments to the Law.

12. We will now implement the above in the dispute at hand. The question is whether the purposes that were described above are more consistent with Merck's interpretation – that the periods of extension orders that were granted after the Israeli order was granted should not be taken into consideration – or with the interpretation of the Manufacturers Association and the Attorney General – that these periods should be considered. In my opinion, the position of the latter is the one that corresponds more completely with what was stated above. It is the position of the legislature that the periods of extension orders granted in the Recognized States all meet the criterion of compensating the patent owners for the periods of time that they lost. If this is the case, the most appropriate compensation, in terms of striking a balance among all of the conflicting values and interests, is the shortest period of time that was granted in one of the Recognized States. It does not matter, in this respect, if the order in the Recognized State was granted before or after the order in Israel. Deviating from the shortest period of time would mean over-compensating the patent owner and prejudicing the generic companies and indirectly, the pharmaceuticals' consumer public. Indeed, changing the period of the order after it

was granted can affect certainty and the patent owners' ability to rely on the order, however the legislature was willing to pay this price in the framework of striking a balance among all the conflicting interests, as detailed in the analysis above.

We should bear in mind how delicate is the balance that must be struck: encouraging research and development as opposed to distributing knowledge; the ethical companies as opposed to the generic companies; the situation in the Israeli market compared to the situation in the international market; the economic interest of the patent owner as opposed to the public health interest. It should be noted that the sensitivity to what is being done in the Recognized States does not derive from mutual respect for the internal decisions of any one state or another. It is rather that the determination of a period of time elsewhere inherently affects what happens here. One cannot ignore the economic reality. It thus follows that the significance of the shortest period of time is that it reflects an appropriate period of time for restricting competition. It should further be mentioned that the recognition of the inventors' bundle of rights also coincides with the interest of the individual who purchases the pharmaceuticals. The approach is that appropriate treatment of the inventor's profit will incentivize the market and expand the basket of pharmaceuticals available to those who need them.

The conclusion is that the interpretation that should be adopted is that when determining the period of the extension order one must also consider orders that were granted in Recognized States after the order was granted in Israel. This is the foundation, but the road to completion of the entire structure is still long. This is the interpretation of the Law, however one must continue to examine whether applying it to Merck unlawfully infringes its proprietary right. And on the other hand, even if there is no wrongful infringement of a proprietary right, the question emerges whether there was reliance upon a legal situation and whether this has significance. We shall now address these matters.

### *The Constitutionality of Shortening the Extension Order*

13. An additional question the parties disputed is the constitutionality of the transitional provisions of Amendment 7 of the Law, which *prima facie*, provide that the calculation mechanism under this amendment will also apply to extension orders that were already granted in the past. This is the issue at center stage in LCA 8263/15, which was filed by Merck. According to Merck, this is a constitutional infringement of its proprietary right, which cannot be justified. We shall begin by presenting the transitional provision:

The provisions of the main law, as worded in this law... shall also apply to applications for the granting of extension orders that were filed before its commencement *and to extension orders that were granted before its commencement*, provided that the validity of the basic patent for which the extension order was granted has not yet expired (sec. 22(a) of the Explanatory Notes to Amendment 7 of the Law – emphasis added).

Merck claims that this is a retrospective act of legislation, since it applies to orders that were already granted, and that it changes a legal situation upon which one could rely. The Manufacturers Association is of the opinion that this is prospective legislation, since the amendment does not infringe the assets that Merck has already accumulated, but rather, at most, infringes its future economic interest, inasmuch as the order should be viewed as though it is to enter into effect only upon the lapse of the twenty-year basic protection. I admit that I am not of the opinion that the dispute regarding the classification is decisive in the case at hand. There are four types of application: retroactive, retrospective, active and prospective (see HCJ 6971/11 *Eitanit Construction Products Ltd. v. State of Israel*, paragraphs 37-38 (April 2, 1013); PPA *Orit Arbiv v. The State of Israel*, IsrSC 46(2) 765, 778-784 (1992)). At times, the legal reality does not cooperate with archetypes. Not every law fits into neat, organized compartments. Even if I were to address the issue as it was presented, it would be incorrect to rule that the amendment is retrospective or retroactive. This being the case, Merck will not benefit from the claim that the current transitional provisions infringe its rights. I shall clarify.

Take, for example, a person who was involved in a work accident on January 1, 2000. In an ordinary situation, his claim would expire under the statute of limitations upon the lapse of seven years. This is the law at the time when his cause of action was established. Let us assume that in 2002 the legislature decides that a claim for work accidents can be filed up to ten years from the date of the accident. A year later, the legislature decides that the period of limitation of actions shall be eight years from the date of the accident. It is further established that all of the amendments also apply to accidents that occurred in the past and for which a cause of action has already arisen. We should take note of the fact that along the legislative axis, from the date of the injury, the person in the example was awarded a benefit in the sense that instead of a seven-year limitation period, the law establishes an eight-year limitation.

It would appear that this example is similar to the case at hand. Merck received a patent in 1994, for twenty years. At that time, the legal mechanism of extension orders, which was legislated in 1998, did not exist. An extension order was granted to Merck in 2005, and the relevant transitional provision shortened the period of extension but maintained the order itself. All of this was done during the twenty-year period. Indeed, alongside the granting of the extension order, generic companies were permitted to begin taking steps toward licensing their pharmaceuticals during the twenty-year period. However, there is an additional fact – in the beginning, the law allowed the ethical companies to look for reference states as they desired, including states that grant maximum extension periods, and this option was later cancelled. All in all, Merck's situation would appear to be better, and it is at least not worse than it was when it filed the patent application.

In my opinion, in both of these examples one cannot say that there is a retroactive or retrospective infringement. The infringement in the statutory provisions can be defined as active, since it applies to a right that exists in the present – a patent – and it operates in the future. It does not apply to an action that has already ended or to a right that has been exhausted. At most, one can say that it has certain retrospective characteristics (see and compare with para. 2 of the opinion of Justice U. Vogelman in HCJ 3734/11 *Chaim Davidian v. Knesset* (August 15, 2012))

(hereinafter: the *Davidian* case)). However, even an active law can infringe property rights, and even retroactive application can comply with the requirements of the law (see and compare: HCJ 4562/92 *Sandberg v. Broadcast Authority*, IsrSC 50(2) 793, 817-819 (1996); HCJ 1149/95 *Arco Electricity Industries Ltd. v. Mayor of Rishon Lezion*, IsrSC 54(5) 547-574 (2000)). It emerges that the title – retrospective or active – is not decisive, nor even appropriate. The situation before us incorporates both retrospective elements and prospective elements. They are intertwined. Meaning that we are addressing an order that was granted in the past but an infringement of a future part thereof, and this is what the discussion should focus on. The title is not a self-sustaining, living being. It is meant only to assist in examining the fundamental question – whether or not we are dealing with a wrongful infringement of proprietary rights. I shall thus focus upon a substantive examination of the elements that are relevant to analyzing the matter, those that are retrospective and those that are prospective, and they shall decide how the constitutional law applies in the concrete circumstances.

1. According to Merck – and pursuant to the *Recordati* case (para. 22 of the judgment) – upon the granting of an extension order, a proprietary right is created. It is argued that if this is the case, then the shortening thereof constitutes an infringement of property that is contrary to Basic Law: Human Dignity and Liberty. On the other hand, the Attorney General's representative and the Manufacturers Association argue that the *Recordati* case held that there is no proprietary right prior to the granting of the order, but it did not establish the opposite position, that the right is created upon the granting of the order,. According to them, the proprietary right crystallizes only upon the lapse of the period of the basic patent right, when the patent becomes protected by virtue of the extension order. According to them, until this stage, there is no vested right that the duration of the order not be shortened.

This requires addressing a basic question. Basic Law: Human Dignity and Liberty explicitly mentions the right to property. The heading of sec, 3 of the Basic Law is "Protection of Property" and its language states: "There shall be no infringement of the property of a person." Section 8 of this law provides that "There shall be no infringement of rights under this Basic Law except...". The question when a person has a right to property and when an economic interest has not crystalized into such a right is a weighty question (see, for example, CA 6821/93 *United Mizrachi Bank Ltd. v. Migdal Cooperative Village*, IsrSC 49(4) 221, 327-331 (1995) (hereinafter: the *Mizrachi Bank* case); Yoseph Edrey, *A Declarative and a Constructed Constitution - the Right for Property Under the Israeli Constitutional Law and its Location on the 'Constitutional Rights' Scale*, 28 MISHPATIM 461, 519-529 (5757) (Hebrew); Aharon Yoran, *The Scope of the Constitutional Protection of Property and Judicial Intervention in Economic Legislation*, 28 MISHPATIM 443, 447-450 (5757) (Hebrew)). In various countries, such as Canada, the right to property is recognized as a protected right in a charter. This situation also derives from internal considerations of constitutional politics (see: David Johansen, *Property Right and the Constitution*, Library of Parliament (Canada), Law and Government Division, (October, 1999)). In any event, this outcome also derives from the difficulty in defining what property is, and in distinguishing between it and an economic interest that is not constitutionally protected. The concern is that a property right will be interpreted in an excessively broad manner, while limiting or frustrating various acts of legislation which have economic implications (see Joshua Weisman,

*Constitutional Protection of Property*, 42 HAPRAKLIT 258, 259-260 (5755) (Hebrew)). The distinction between an economic interest and a property right is a general issue, and it is implemented in each of the fields of law while striking a balance between the interests and values at issue. This is also the case in the field of intellectual property in general, and in the area of patent law, in particular.

At present, I do not need to set hard and fast rules as to whether granting an extension order creates a proprietary right in order to rule in the matter at hand. The case law has already held that, as a matter of principle, a patent is a proprietary right (see, for example, the *Merck* case, para. 17; HCJ 5379/00 *Bristol-Myers Squibb Company v. Minister of Health*, IsrSC 55(4) 447 (2001)). I am willing to assume for Merck's benefit that an order to extend the patent is included in this right. However, the case before us does not address the matter of the cancellation of an extension order. The question before us is different: What is the law that governs the shortening of an extension order? One can even pinpoint the issue: What is the law that governs shortening an extension order in the current circumstances, in which Merck's patent was registered before Amendment 3 of the Law, and before the institution of extension orders, along with its purposes, was established? Does such a right include a constitutional protection not to have its duration changed? This framing of the question is what leads to rejecting Merck's position that its proprietary right was unlawfully infringed. I shall clarify my position.

15. Should all legislation that has economic implications be examined through the prism of the constitution? This question is at the heart of the discussion that surrounds the nature of the constitutional right to property. As early as the *Mizrachi Bank* case various positions were expressed regarding the nature of the right. As is well known, that case concerned a challenge to a provision of law that somehow infringed the possibility of collecting various types of debts. President (Emeritus) M. Shamgar ruled that for the purpose of the constitutional examination, an obligatory right should also be considered property (*ibid*, page 328). An apparently more expansive approach was expressed by President A. Barak. According to him, "property is any interest, which has an economic value". However, the question whether any governmental action that affects the value of an individual's property requires a constitutional examination remained to be further discussed. It was additionally ruled that *de minimis* infringements would not necessitate a constitutional examination (*ibid*, pages 431-432). From a different direction, Justice I. Zamir expressed a more cautious approach, pursuant to which it is not desirable to define any infringement of a person's financial income or the value of his property as an infringement of property. However, he assumed for the purpose of the ruling that the legislation that was the subject of the dispute did infringe a right to property since according to him, even under this assumption, the case concerned an infringement that passed constitutional review (*ibid*, pages 470-471). This pattern of deciding, and in fact of avoiding decision, repeated itself in various contexts in which economic legislation was subjected to review. The conspicuous example is that of tax legislation in which the Court has chosen to analyze the cases brought before it on the assumption that the legislation infringes a right to property, without ruling on this matter (see an example of this in the *Davidian* case, para. 29 of the opinion of President M. Naor, and the survey there).

I will already state that the case before us does not require an extensive

discussion of whether the transitional provisions of Amendment 7 infringe Merck's right to property in a manner that requires a constitutional review. Even if that were the case, there is no unlawful infringement. In my opinion, this is not a borderline case, and there is no need for an elaborate analysis of the elements of the Limitation Clause. This is a case of primary legislation for a proper purpose – encouraging one of the fields of industry and reducing the price of pharmaceuticals for the entire public. The extensive analysis that was performed above, in the framework of LCA 8127/15, leads to the conclusion that the proportionality condition is also met in all of its senses, including in its narrow sense. The compensation which Merck was awarded in the form of the new extension period that was determined in the order is appropriate and realizes the purpose for which the arrangement was enacted. Merck's complaint was not directed at the duration of the period itself, but to the very shortening thereof. That being the case, in a broad examination, Merck's economic situation was not harmed. What was harmed was the possibility that it may be improved. The legislature is the one that granted it that possibility, and it is the one that subsequently took it away, without worsening Merck's overall situation (and we will already preempt and say that no reliance whatsoever of Merck on the legal situation prior to Amendment 7 of the Law was either argued or proven). We would note that at the time when Merck registered its patent, the arrangement of extension orders had not yet been enacted. Thus, the scales clearly tip toward realizing the purposes of Amendment 7 of the Law. In any event, Merck's arguments in this context – both interpretational and substantive – are to be rejected. It should further be noted that I did not find merit in its arguments that related to flaws in the legislative proceedings that preceded Amendment 7 of the Law, and I suffice in referring to our discussion above in LCA 8127/15.

16. However, and in this sense, above and beyond that which is necessary, it is appropriate to refer briefly to the question whether we are addressing an infringement of the right to property that requires constitutional review. And the end of the last sentence should be emphasized. The important question when addressing legislation that has economic implications is not necessarily whether there is an infringement of a right to property, but rather if there is a *constitutional* infringement of a right to property. As already mentioned, in the *Mizrachi Bank* case President Barak already addressed the possibility that there could be an infringement of an individual's property that would not require a constitutional review of the law when only a *de minimis* infringement was involved. In HCJ 2442/11 *Adv. Chaim Stanger v. Speaker of the Knesset* (January 12, 2011), one can see an additional development of constitutional review. One of the issues addressed in the judgment was the constitutionality of a statute that revoked the possibility of filing a third-instance appeal as of right in various detention matters. Instead of a third-instance appeal as of right, the possibility of applying for leave to appeal was provided. President A. Grunis made an *obiter dictum* distinction between the "constitutional threshold", which is the lower threshold beneath which there will be a constitutional infringement, and the "legal status". I would prefer to define the distinction between a constitutional infringement and an infringement that is not constitutional. As President Grunis stated, there are laws that are above the constitutional threshold, where even if their amendment harms an individual, they are still not exposed to constitutional review:

There is no doubt that the amending law

discussed in the petition adversely affects, to some degree, the state of suspects and defendants as compared to the previous legal situation. However, the mere adverse change does not necessarily lead to the conclusion that there is an infringement of a constitutional right... We must distinguish between the *constitutional threshold* and the *legal status* preceding the amendment to the Law... The fact that the Law was amended and lowered the *legal* threshold does not, in and of itself, lead to the conclusion that the *constitutional* threshold was infringed with the adoption of the amendment to the Law (para. 45).

It is possible that in relation to the previous law, a right that was granted to a person is taken away, while in relation to the Basic Law, there is no infringement that justifies constitutional review. This holds true even with respect to the right to liberty – in matters of detention – and so with respect to the right to property.

HCJ 5998/12 *Guy Ronen v. Knesset* (August 25, 2013) addressed a statutory provision that changed the mechanism for calculating the pension allowance of some IDF retirees. The petitioners argued that the new calculating method would lead to giving allowances of amounts lower than they would have received in accordance with the previous calculation method. President Grunis reiterated his position, and in an even more precise manner:

The amendment of a law after the legislation of the Basic Law must be examined with respect to the constitutional threshold that is determined by the Basic Law, and not in relation to the legal state that preceded the amendment of the law. It should be noted that the cases that are prone to such confusion are cases in which the law that is being constitutionally reviewed changes an existing law or constitutes an amendment to an existing arrangement. It is clear that in a situation in which a new law is enacted in a matter that until such time was not regulated by statute, no concern arises that the amendment will be examined in relation to a preceding legal state (para. 14. My colleagues Justice Y. Danziger and Justice Z. Zylbertal concurred).

Thus, the examination is not whether a person's property (in the broad sense given this term in the *Mizrachi Bank* case) was infringed, but rather whether the constitutional threshold was crossed, in which event the infringement must be examined through the prism of the constitution.

In the framework of the discussion in LCA 8127/15 we saw that the

calculation mechanism established in Amendment 7 of the Law, in and of itself, leads to an appropriate result. Merck does not argue that the period of the extension order granted in the United States was too short, but rather that the legal situation changed. But it emerges from the above analysis that the situation that preceded Amendment 7 – in the framework of which a patent owner could choose the state that granted the longest extension period as the reference state – is one that benefited it in a manner that exceeded what is necessary. In other words, if the substantive provisions of Amendment 7 – which have not given rise to any objection – are above the constitutional threshold, then the legal situation that existed before them was certainly above this threshold. In the circumstances of the specific statutory development of the case before us, the constitutional threshold was not crossed.

17. Incidental to the discussion, I shall address the issue of the significance of specific reliance on the part of the patent owner upon an extension period that was retroactively cancelled by a statutory amendment. The argument of reliance and adverse change is an argument that is independent and separate from the argument of unconstitutional infringement of property. It can be argued that if and to the extent specific reliance by Merck on the legal situation that was changed can be proven – it may be, without setting a hard and fast rule in the matter – then it is possible to initiate an appropriate proceeding, pursuant to the rules of administrative law, in the framework of which the relief that would be granted could also take the form of compensation for damages that were caused, and not necessarily the granting of a patent right (see and compare the *Davidian* case, paras. 21-26; Daphne Barak-Erez, *Protecting Reliance in Administrative Law*, 27 MISHPATIM 17 (5766) (Hebrew)). In the current proceeding, Merck did not raise an argument of concrete reliance on the statutory situation, and therefore the question is theoretical. It should be noted that the Attorney General's representative argued that in light of the nature of the extension orders and their subjection to changes due to events that occur after they are granted, reliance on the period of the extension, at least before the order becomes operative upon the lapse of the basic patent period, is not protected. This is a fine question, but it can be left to be addressed in due course since, as noted, in the present circumstances and the current proceeding, reliance on a legal situation that was changed was neither argued nor proven.

18. For the purpose of enriching the discussion, while addressing the essence of the economic aspect, it would be appropriate to add a comment focusing on the nature of Merck's rights. To be clear, the ruling in this judgment does not depend on the various remarks in the following paragraphs, however they would seem to reinforce the result I have reached.

In practice, no one disputes that Merck does not have a *property* right in the traditional sense. At most one can say that it has a right to *intellectual property*. This is the prism through which one must view the matter. Intellectual property laws are different, for example, from real estate laws or tax laws in terms of defining the property right. As opposed to a property right in a physical object, which prevents another person from taking the object from its owner, or tax laws that allow the authority to take funds that the citizen accumulated – an intellectual property right is no more than a prohibition forbidding another from performing a certain action, even when the performance thereof does not prevent the owner of the right from performing an identical action. The objective of the prohibition is not the



preservation of the safety of the owner of the right or of his property, but rather of his ability to generate more profits in the future – if only to cover past investments. It is therefore interesting to ask what is the source of the justification to impose prohibitions upon the general public, even when no harm might be caused to another's negative freedom or to the property he has accumulated? The dispute between legal systems and philosophers regarding the status of intellectual property laws, including patent laws, is well known. One approach seeks to base them on a kind of natural right of the creator, who labored on his creation, to reap the fruits of his labor. Another approach focuses on general policy considerations, primarily incentivizing the development of patents, the creation of works, etc., for the sake of creating a more efficient, higher quality market (see, for example, Daphna Lewinsohn-Zamir, *The 'Fair Use' Defense in Copyrights*, 16 MISHPATIM 430, 430-431 (5746-5747) (Hebrew); Wendy Gordon, *On Owning Information: Intellectual Property and the Restitutory Impulse*, 78 VA. L. REV. 149 (1992); Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988)).

In any event, the intellectual property right is special. It is a challenging question whether the uniqueness derives from its relative novelty – a fact that may change; or from other special reasons whose persuasiveness will stand the test of time. The intellectual property right presently primarily focuses on loss of future profits and not on protecting against direct harm to existing property. There are those who are of the opinion that the interest of preventing loss of profits is less positively protected by the law, and there are those who have even attempted to justify this on a normative level (see Eyal Zamir, *Loss Aversion and the Marginality of the Disgorgement Interest*, SHLOMO LEVIN VOLUME 323, 368-372 (Asher Grunis, Eliezer Rivlin & Michael Karayanni, eds., 2013) (hereinafter: Zamir, *Loss Aversion*) (Hebrew)). It has been explained that harm such as the expropriation or trespass of land, and the taking of property by a tax mechanism carries heavier psychological weight than the loss of profits (such as the removal of patent protection, which allows competition and causes a decline in profits from the sale of a product). This phenomenon is referred to as loss aversion (see, in a general manner, EYAL ZAMIR, LAW, PSYCHOLOGY, AND MORALITY: THE ROLE OF LOSS AVERSION (2015) hereinafter: ZAMIR, LAW, PSYCHOLOGY AND MORALITY)). The more we are in the realm of loss of profits, the harm to the potential profiler is of lesser magnitude than the harm to a person who suffered injury. Intuitively, and even without relying on research, the expropriation of an object by the authority is deemed more offensive than the denial of the option of receiving an object in the future. It is interesting, in this context, that Prof. Zamir wrote that it is possible that the loss aversion phenomenon does not necessarily reflect the objective value of objects and rights. It is possible that were we all rational people – as those theoretical creatures that perform transactions in the research of some economists – there should not be a principled difference between the realm of damages and the realm of loss of profits. However, since psychology is what it is, this is of considerable and significant weight (Zamir, *Loss Aversion*, pp. 370-372; ZAMIR, LAW, PSYCHOLOGY AND MORALITY, pp. 205-207).

19. An additional aspect of intellectual property is the distinction between the core and the margins. We have mentioned the various approaches that justify the law's protection of intellectual property. Without delving into the thick of it, it is obvious that even those who support the "natural" approach leave considerable room

for policy considerations. This is *a fortiori* the case when addressing the "margins" of intellectual property arrangements, which reflect policy considerations and not necessarily property rights that prevail over the policy considerations (see, for example, the *Merck* case, paras. 17-27; Daphna Lewinsohn-Zamir, *Economic Considerations in Protecting Inventions*, 19 MISHPATIM 143 (1983) (Hebrew); and compare, MIGUEL DEUTCH, COMMERCIAL TORTS AND TRADE SECRETS 699 (2002) (Hebrew)). The question before us is whether the shortening of the protection period of an intellectual property right is an infringement of a right to property. In other words, the question does not relate to the mere existence of the right, but rather to outlining its boundaries. The right exists, but it is not clear what is included therein to begin with and how its exact limits are defined.

Take as an example a petition to expand the protection of the basic patent from twenty years to twenty-two years, on the grounds of a constitutional infringement of property. Obviously such a petition would be dismissed. Analytically speaking, how is this different from a claim due to the shortening of a period of a patent from twenty-two years to twenty years (assuming there is no specific reliance on the duration of the period)? The difficulty in defining the precise boundary stems from the fact that intellectual property is an idea and not an object. Therefore, the mere definition of the intellectual property right is not sharp and precise. Its boundaries can be changed by their very nature, as opposed to those of objects for which the physical reality prescribes their exact size. This question can emerge in various contexts that address abstract ideas. For example, in criminal law, does a statutory amendment that allows imposing longer imprisonment on the perpetrator of a certain offense require constitutional review? What are the boundaries of the right to freedom? The precise boundaries were, of course, prescribed based on the legislature's policy considerations, and they are more exposed to changes. This determination is particularly apparent when addressing patent laws, which are at the center of the technological stage. This requires that they react quickly to various events and developments – even more so than other intellectual property fields – such as the protection of trademarks or literary works. In the dynamic environment of technological developments, innovations and inventions – and especially in a global world in which competition crosses virtual and physical borders – the boundaries of the right must also be dynamic.

This is the foundation of the extension orders arrangement. It is not a "rigid" arrangement that creates a representation of an irreversible right, but it is rather a dynamic arrangement that is given to certain changes to begin with. The most conspicuous example of this appears in sec. 64J of the Law, which provides that an extension order can be cancelled due to a subsequent extension order being granted in a Recognized State. Indeed, the cause for expiration in this section is the expiration of the patent in another country, but ultimately, in the prism of exposure to change, Merck was aware, as early as at the time of receiving the order, that orders that may be granted in other countries could lead to the shortening of the period of the order that it was granted. At issue is an expansion of the possibility that the order may be shortened – a possibility that had already existed. To begin with, it was not an irreversible right that was granted, but rather a right dependent upon orders granted overseas. In the case at hand, the transitional provisions in Amendment 7 of the Law explicitly provide that the amendment will only apply to those whose basic patent period had not yet expired. Anyone who already received the patent's

protection by virtue of the extension order was not harmed by the amendment.

*A Comparative Perspective*

20. It would be informative to turn to Jewish law's approach to patent laws, and along the way we will also mention the pharmaceutical field. We shall begin with recognizing the inventor's proprietary status. Conceptual caution is necessary here. Rabbi Isaac Halevi Herzog (one of the two first chief rabbis of the State of Israel, along with Rabbi Ben-Zion Meir Hai Uziel, d. 1959) emphasized in his monumental book about property laws in Jewish law, that due to the nature of the Jewish law system – from the written Torah to the oral law, the Mishna and the Talmud, and up to the Responsa that continue to be written to the present day – the development of the law is based on concrete examples. It is difficult to find a direct definition in its sources for the right to property in general, and certainly for the right to intellectual property. However, Rabbi Herzog insisted that it is possible to find the intellectual nucleus that, at least in general terms, could guide the Halakha:

It should be made clear once more, that even the sources adduced above would furnish no firm legal ground for patent-right. They would merely supply the spirit and the trend which would have to be clothed with the body and substance of *takkanoth*, of legislative enactments... Had disputes about such matters been of relatively frequent occurrence, they would have found an echo in our juristic literature, and although, as already stated, there is no direct ruling or dictum in the *Talmudim* on patent right, there is in that ocean of Jewish law and lore enough of the basic moral idea and even of a legalistic nucleus to have supplied the authorities with material for dealing with the question from the *halakhic* standpoint. I have no doubt that under Jewish law had the question become actual, patent-rights would have been protected in some measure, at least by special enactments supported by certain *Talmudic* analogies (ISAAC HERZOG, *THE MAIN INSTITUTIONS OF JEWISH LAW 1: The Law of Property* 132 (1939)).

Indeed, the Sages labored and found rich, interesting sources and precedents. Rabbi Shimon Shkop (Head of the Grodno Yeshiva who lived in Europe and died in 1939), at the beginning of his commentary to the Talmud tractate *Bava Kamma* – which relates to damages – referred to one of the heads of damages in the Talmud, the pit. The question is on what grounds can a person who dug a pit in the public domain be found liable for the injuries of a person who was injured thereby. At first glance it would appear that the person did not cause harm by his body or property, since the pit is located in the public domain. Rabbi Shkop explains as follows:

And in the case of a pit, the Torah held him liable

for the injury caused by his harmful thing, and that the pit is his is due to the digging and the opening. That is, he prepared the harmful thing and he is therefore called its owner, similar to that which concerns a person's right: it is accepted under the laws of the Torah and the laws of the nations that whoever invents something new in the world is the owner of all rights thereto – similarly, the Torah called a person who prepares a harmful thing the owner of the pit and the owner of the fire, and held the owner of the harmful thing liable (NOVELLAS OF RABBI SHIMON SHKOP, *Bava Kamma* 1. See also LCA 7337/12 *Amir Cohen v. John Deere Water Ltd.*, para. 6 of my opinion (March 12, 2013)).

The principle that emerges is that "whoever invents something new in the world is its owner". This is the linkage between the owner of the invention and his invention. Rabbi Shkop repeats this principle elsewhere, when he addresses the possibility of gaining ownership by thought and invention: "Also a thing that was created by a person's wisdom belongs to such person... who also was awarded with the instrument of thought, to benefit from what he shall invent therewith... and since he has sold him his wisdom, meaning his body and limbs that invented this thing in the world – then immediately when such thing enters the world it belongs to the buyer (NOVELLAS OF RABBI SHIMON SHKOP, *Gittin* part 4; see Rafi Reches and Michael Wigoda, *Protecting Copyrights, Patents and Inventions in the Jewish Law*, Ministry of Justice (2010)).

Rabbi Herzog was of the opinion that one can already find an anchor to the rights in a new invention – and in fact, a patent – in the Babylonian Talmud and its commentaries. One of the issues addresses a person who wants to cast a fishing net near a place where a trap had already been set by another person. It was ruled that he must distance it from that of the other: "Fishing nets must be kept away from the fish the full length of the fish's swim. And how much? Rabbah son of R. Huna: Up to a *parasang*?' (*Bava Batra* 21b). The Talmud commentators discussed the basis for prohibiting the competing fisherman from laying down his trap – since the fish have not yet been caught by the first fisherman, and therefore, *prima facie*, they have not yet become his property. One of the explanations is presented by the Tosafist Rabeinu Meir of Ramerupt (Ashkenaz, 11<sup>th</sup> century).

Rabbi Meir, Rabeinu Tam's father, says that this is a dead fish, since the fishermen would place a dead fish in their nets so the fish would gather around such fish. And since he was the first to cast his net, and due to his act the fish were gathering around – if the other were to cast his net, it would certainly be as though he was stealing from him (*Kiddushin* 59a).

According to Rabeinu Meir, the fact that casting the net requires prior thought and

action entitles the person who cast the net to a proprietary right in the anticipated profit even though this profit has not yet been realized and the fish have not yet entered his possession. According to Rabbi Herzog, one can view this source as an anchor for the protection of patents: "Here at last we have some approach to the idea of patent-protection" (page 131).

Rabbi Asher Weiss (a contemporary Jerusalem scholar) also ruled on the matter of the halakhic validity of a registered patent: "It is my humble opinion that it is a simple position that a person also has a monetary right in the fruit of his spirit and creation, and what he conceived is not less than what he acquired, and just as the fruit of the palm belong to the owner of the palm, even though he did not acquire them through the routes of title, so the fruit of his spirit belong to him and there is no need for title." He therefore ruled as a matter of Halakha that "[in] a registered patent, it is clear that according to the law of the Torah, others are prohibited from doing as is set forth therein (RABBI ASHER WEISS, DARKHEI HORAA 4, 100 (5766)).

21. However, alongside the recognition of the proprietary, or quasi-proprietary right that a person has in his inventions, we find resonances in Jewish law to the fact that this right is not unlimited and that it must be balanced with the public interest of having knowledge resources available to all. The Mishna tractate *Yoma* gives a list of craftsman who did not agree to reveal the secret of their craft to others, while denouncing this:

And these they mentioned to their shame: those of the House of Garmu [who] did not want to teach about the act of the shewbread; those of the House of Avtinas [who] did not want to teach about the act of the incense; Hygros, son of Levi, knew a chapter in song but did not want to teach; Ben Kamtzar did not want teach the art of writing; ... It was said about the above, the name of the wicked shall rot (*mYoma* 3, 11).

The Babylonian Talmud explains why the Sages required that the craftsmen reveal their secrets: "When the Sages heard that, they said: whatever God created was created in His honor. As it was said: 'Anyone that is called by my name, I have created in my honor' (TB *Yoma*, 38a). This is a religious approach that emphasizes the fact that the natural – material and corporeal – resources are universal because they were created by God. It is inappropriate to attribute them exclusively to any specific entity. This is the case with respect to all natural resources, and *a fortiori*, with respect to a resource that has the potential to heal. As told in the Babylonian Talmud in tractate *Avoda Zara*:

Rabbi Yochanan suffered from the *tzefidna* disease. Hhe went to a Roman matron who prepared a remedy on Thursday and on the eve of the Sabbath. Rabbi Yochanan asked her: What will I do on the Sabbath? She responded: You do not need a remedy on the Sabbath. He asked her: What will I do if I do, nevertheless, need a

remedy? She responded: Swear to me that you will not reveal the recipe and I will give it to you. Rabbi Yochanan swore "to the gods of Israel that I will not reveal". Rabbi Yochanan left and gave a public sermon in which he revealed how the remedy is prepared.

Even though Rabbi Yochanan swore to the Roman matron that he would not reveal her secret, Rabbi Yochanan broke his vow due to the public interest in healing, and revealed the Roman matron's healing secret to the entire public (in the Talmud there is reference to the question whether this amounts to desecrating the name of God).

22. It should be noted that we are dealing with patent laws. Even according to Israeli law, patent laws are characterized by their application to an invention "that is a process in any technological field, that is new, useful, can be used in industry and constitutes inventive progress" (sec. 3 of the Law). From the Jewish law sources it emerges that the justification for protecting the patent derives from the creation. In this sense, there were those who said that just as the works of a person's hands belong to him, so do the inventions of his imagination and the implementation thereof. According to this approach, a creation – either of the hand or of the head – entitles a status of "ownership" with respect to the invention and its fruits.

An example of an invention in the pharmaceutical field was cited. Rabbi Herzog emphasized that our Sages did look kindly on a person's wish to keep the invention to himself forever. This is due to the recognition that what is concerned is an invention that can save lives (*ibid*, page 128). The tension that was presented in the above analysis is expressed in the fact that the craftsman has a right to receive money, but is not entitled to keep the patent secret to himself, certainly not forever. One can say that patent rights do not override patients' rights (in the broad context, see NIMUKEI YOSEF AL HAROSH, *Yevamoth* 12a; RITVA (Rabbi Yom Tov Ben Avraham Asevilli) ON THE BABYLONIAN TALMUD, *ibid*; Rabbi Herzog's position, *ibid*, page 129).

It is interesting to note that the adjudicators that were cited – Rabbi Shkop, Rabbi Herzog and Rabbi Weiss – lived between the 19<sup>th</sup> and 21<sup>st</sup> centuries. During this period the field of patents has become much more sophisticated. The words of Prof. Edward Fram, an expert on history, halakha and its development, are relevant in the case at hand: "like rabbis in all periods, ...rabbis had to address the needs of the marketplace in order to keep the halakhah relevant and maintain the integrity of Jewish life" (EDWARD FRAM, IDEALS FACE REALITY – JEWISH LAW AND LIFE IN POLAND 162 (1997)). Indeed, the economic question directly relates to the Jewish community in general, and in the State of Israel in particular. Integrity is maintained by the fact that the Rabbis based their conclusions on the principles of halakha and on Talmudic sources. The theoretical foundation is not, essentially, economic, but rather the recognition of the person's abilities to create and the link between him and his creation, while considering the needs of society. It appears that the religious foundation is "and you shall walk in His ways" (Deuteronomy 28, 9) – What He (God) creates – you (man) also create. The justification for legal recognition is thus perceived as both moral and practical.

23. We now proceed from a broad perspective to a narrower one focusing on American law with respect to the specific arrangement of extension orders, their background and the method of their calculation. The basic rule in the United States is also that a patent's protection is for twenty years from the date the application for the patent registration was filed (see 35 U.S.C § 154(a)(2)). However, an exception to this rule was provided in the form of the possibility of granting an extension order ("Patent Term Extension", see The Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282) (hereinafter: the Hatch-Waxman Act).

The rationale behind this exception is similar to the process that led to the corresponding Israeli arrangement. The Hatch-Waxman Act was enacted against two backgrounds: On the one hand the Act addresses the problem of the generic industry. As in Israel, the American industry was also facing difficulty in competing in the free marketplace with other pharmaceutical companies immediately after the patent expiration since, according to the rulings of the courts at that time, it was not possible to perform various actions required by the regulator to license a patent-based product as long as the patent had not expired:

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement... even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval... Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's de facto monopoly would continue for an often substantial period until regulatory approval was obtained" (*Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 670 (1990) (hereinafter: the *Eli Lilly* case).

This problem was resolved by sec. 35 U.S.C § 271(e)(1) of the law that provides as follows:

It shall not be an act of infringement to make, use... or sale... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological product"

On the other hand, the arrangement of extension orders was provided for patents for which the patent owner is required, as a condition for marketing, to perform various licensing actions that take a significant amount of time (see 35 U.S.C. § 156). In the United States, as in Israel, both of these arrangements were perceived as different

sides of the same coin. On the one hand, the need to open the market to competition at the time of the patent expiration; on the other hand, compensating the patent owner for "lost" time". A fine example of the tight connection between the two arrangements can be found in the *Eli Lilly* case. In that case, which was heard by the Supreme Court, a question emerged whether a certain medical device was covered by the section that allows performing licensing actions even before the patent's expiration. The federal court's answer was negative, however this ruling was reversed by the Supreme Court in light of purposive interpretation of the law. The ruling was based on two facts. First, the device at issue was required to undergo various examinations as a condition for marketing. Second, it was possible to receive an extension order in that field. The Court held that as a rule, and since these are related arrangements, it would not be possible to benefit from both of them. If it is possible to receive an extension order, the competitors would be able to take actions toward licensing during the period of the patent, and *vice versa*, in light of the tight linkage between the two arrangements:

It seems most implausible to us that Congress, being demonstrably aware of the dual distorting effects of regulatory approval requirements in this entire area... - the disadvantage at the beginning of the term producing a more or less corresponding advantage at the end of the term - should choose to address both those distortions only for drug products; and for other products named in 201 should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating distortion of the 17-year patent protection. It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence here (*Eli Lilly*, p. 672).

As can be seen, it is one earth. The difficulties in Israel and the United States are common, as are the solutions – both for the generic industry and for the ethical industry.

To conclude, we will turn our glance towards the method of calculating the period of the extension order in the United States. As noted, in Israel there is a distinction between a situation in which the licensing of the patent was requested only in Israel, and a situation in which licensing was requested in an additional Recognized State. In the first case, the period of the order is the time the licensing procedure lasted, from the date the application was filed until the license was granted. In the latter case, there is a linkage to the shortest extension order that was granted in one of the Recognized States. The calculation mechanism in the United States is also based on the period of the licensing process, although in a more complex manner. It is based on the duration of the testing phase and the approval phase. The testing phase is the period from the date when approval for experimenting



on humans was received and until the date the new drug application form was filed. The approval phase starts at this stage and continues until the final approval of the pharmaceutical (see 35 U.S.C. § 156). There are a number of scenarios and calculations, and there is no need to specify all of them in the framework of this judgment. Suffice to say that the main rule is to grant an order for the period of half of the testing phase together with the entire approval phase (*ibid*). As in Israel, there are various restrictions that apply to the length of this period, and particularly that it be for no more than five years in total, and no more than 14 years from the day the marketing approval is granted.

This is the current calculation in principle, without addressing all of the legislative changes that have also occurred in the United States. One can now understand the legislature's decision to view equating the period of the Israeli order with the U.S. order as appropriately compensating the patent owner. This, as noted, is the situation in Merck's specific case. This is what we have said in light of the global aspect of the use of pharmaceuticals. There are countries that legislate their laws on this matter with one eye looking inward and one eye examining what is occurring in other countries. That is the demand of the economic reality in striving to give proper weight to all of the factors involved in what occurs in this field, including the individual.

### *Conclusion*

24. The transitional provisions of the Israeli law do not amount to retroactive infringement. Even if the shortening of the period of the extension infringes a constitutional right, it clearly passes constitutional review under sec. 8 of the Basic Law. Finally, there are solid grounds for the conclusion that the infringement does not reach the constitutional threshold. As was explained above, not every infringement is necessarily a constitutional infringement. The legislature gave and the legislature took back its share. I am not saying that this conduct, or such legislation, is immune to constitutional review. However, it must be grounded. In the example of the third-instance appeal by right that was discussed above, had the legislature provided that there is a right of appeal in the Tel Aviv district but not in the Northern district, it could have been argued that we were concerned with a constitutional infringement. This is certainly so in the case of wrongful discrimination.

As noted, in this case the purpose is to grant appropriate compensation to the patent owner, in the form of a period of protection that exceeds twenty years, but in a manner that does not excessively prejudice other important interests and values, such as opening the market to competition. Viewed as a whole, the actual period of protection that Merck was awarded is longer than that to which it was entitled when the patent was registered. Not a hermetic twenty-year unit, but rather a longer cumulative period of time that includes the period of the extension order. The shortening of the extension order relies on a calculated, considerate policy of the legislature. This is true with respect to the ethical companies. This is true with respect to the generic companies. This is true with respect to the public. There is a proper dynamic between the situation in Israel and in the overseas markets.

25. It is possible that had LCA 8263/15 stood on its own, it would not have been

appropriate to grant leave to appeal. However, due to the material connection between the two applications, and once it was decided to hear LCA 8127/15 on its merits, I would recommend to my colleagues that leave to appeal be granted in both of the cases. I would further recommend that we hear LCA 8263/15 as though leave had been granted and an appeal filed pursuant thereto, and to deny the appeal on its merits, while accepting the appeal in LCA 8127/15 as follows:

In the dispute in LCA 8127/15 between the District Court and the Registrar, my opinion is as the opinion of the Registrar, that the extension order that was granted in the United States is the relevant reference patent extension order in the circumstances of the matter. Accordingly, I would recommend to my colleagues that we rule that the period of the extension order that was granted to Merck has expired. In the circumstances of the matter, Applicants 1 and 2 shall bear the Manufacturers Associations' expenses and legal fees in the amount of NIS 125,000.

**Justice Y. Danziger**

I concur.

**Justice U. Shoham**

I concur with the comprehensive, thorough opinion of my colleague Justice N. Hendel, and I agree to granting the appeal in LCA 8127/15 such that the period of the extension order that had been granted to Merck has expired.

Decided in accordance with the opinion of Justice N. Hendel.

Given this 9<sup>th</sup> day of Sivan 5776 (June 15, 2016).