专利、强制许可和药品可获取性：最新经验

许国平
(Martin Khor)

TWN
第三世界网络

更新版

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Third World Network

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致 谢

这是2007年在玛伊多王子奖大会上提交的论文《促进基本健康技术的可获取性：关注被忽视的疾病，惠及被忽略的人群》的修订稿。这次大会是由玛伊多王子奖基金会、泰国卫生部、世界卫生组织、玛伊多大学医学院和Siriraj医院于2007年2月1日至2日在泰国曼谷联合举办的。

本文援引了其它各类文献。第一章和第二章引自Khor (2004)。第三章的框架和部分内容引自 Sangeeta(2007a)，而各国案例的材料引自Chee（2006a）(泰国)，Chee (2006b)(马来西亚)，Love (2007)（意大利和美国)，Lutfiyah和Hira（2006）（印度尼西亚）和Sangeeta（2007b）(巴西)。第四章引自Khor（2007）和无国界医生（2004）关于FTA部分和Smith（2007）关于泰国人权委员会的报告。

本文由Chee Yoke Ling作了补充更新。

前　言

世界各地的公民社会团体和发展中国家政府关于确保有及时途径获取可负担药物的共同努力大约开始于 15 年前，这很大程度上是由 HIV/AIDS 携带者和患者急需的抗逆转录病毒药物的价格畸高引发的。对该群体而言，获取可负担的抗逆转录病毒药物是生死攸关的问题，而价格高昂是因为制药企业持有药品专利。

无国界医生和世界卫生组织等机构最先提醒国际社会关注这一危机。2001 年，40 多家制药公司包括最大的全球公司起诉南非政府，因其颁布的一部法律允许进口和本地生产专利药品的仿制药。这震惊了世界，并促成世界贸易组织紧急召开激烈的政府间谈判，确立公众健康权优先于药品专利权的原则。随之而来的是一直持续到今天的关于药品可及性的强烈的全球公民社会运动。

在《与贸易有关的知识产权协议》(TRIPS 协议)颁布之前,没有一部国际法律要求国家对药品授予专利。几乎所有的发展中国家都不承认药品专利虽然他们可能对药品生产过程授予专利。依据 TRIPS 协议，专利保护最短期限为 20 年成为一项义务。然而，专利人的私有特权与公共利益间的平衡问题在许多方面依然存在。

2001 年的 WTO 部长级会议发表的《TRIPS 与公共健康多哈宣言》重申了成员国有权通过各自国内专利法使用一些“灵活性”。其中之一是在以合理的价格请求专利持有者自愿许可其进口或生产专利产品的协议没能达成的情况下，可以颁布强制许可。

尽管有这些法定权利，发展中国家颁布强制许可仍会引发批评和压力。因此，一些发展中国家行使他们的权利实施强制许可,尤其是许可“政府使用”，是非常鼓舞人心的。其中一种强制许可是颁发给政府，以获得仿制药物供公立医院和诊所使用。

尽管抗逆转录病毒药物(ARVs)是2001年后许多强制许可的主体，

但 2007 年泰国颁发许可允许国内生产氯吡格雷用于治疗冠状动脉疾病，仍具有重大意义，是公共健康的一次胜利。

《专利、强制许可和药品可及性》中译本介绍了一些近期实践，包括马来西亚、印尼、泰国、津巴布韦和加纳的经验。此外，美国和意大利近期颁发非抗逆转录病毒药物强制许可表明这一重要的公共健康工具也被发达国家所用。此书还收录了发展中国家实际颁发的强制许可的副本。

我们希望本书有助于中国在如何利用 TRIPS 协议灵活性这一问题的讨论，TRIPS 协议的灵活性已被纳入中国修正后的专利法。

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目　　录

专利、强制许可和药品可获取性：最新经验

一、背景

药品可获取性，作为人类健康权的一部分，已经成为公共健康的一个主要议题了，特别是专利对药品价格产生了极大的影响。在世界贸易组织（WTO）《与贸易有关的知识产权协议》（TRIPS）（1995 年）签署后，药品专利变得更加普遍。这一协议强制要求 WTO 成员方将药品纳入其产品专利和方法专利制度中。

几年前，当公共卫生和发展组织指出专利所赋予的垄断权力使得治疗艾滋病的药品价格一直都维持在相当高的水平时，公众反对声很大。在发达国家，每年使用专利药品治疗一个病人的费用为 10000－15000 美元，而一些发展中国家的药品生产商可以提供低至 300 美元的仿制药，现在费用更降到 100－150 美元。如果发展中国家能低成本生产或进口这些仿制药，那么将大大增加对药品的可获取性。

尽管 WTO 成员方不得不允许药品专利，但 TRIPS 协议确实也留有很多灵活性。比如，如果专利药品的价格过高，政府当局可以采取措施，如为某一机构或企业颁发强制许可用于制造或进口该专利药品的仿制药，这样病人获取药品的价格会大大降低。

2001 年，多哈 WTO 部长级会议通过了《关于与贸易有关的知识产权协定和公共卫生的多哈宣言》作为对公众关注焦点的一个回应。《宣言》重申并阐明了 TRIPS 协议下的灵活性，指出："我们同意 TRIPS 协议不能够也不应该妨碍各成员采取措施以维护公共健康。……我们确认该协议能够也应该在解释和执行方面支持 WTO 成员维护公共健康的权利，特别是促进所有人获得药品的权利。"《宣言》清楚地说明了 WTO 成员方可以充分使用的一些灵活性，比如颁发强制许可的权利以及可以自由地决定颁发强制许可的理由。

如果《多哈宣言》意欲使艾滋病患者以及发展中国家患有其它疾病的患者受益，这些国家现在必须在本国的专利立法中制定适当的条款

“充分”使用 TRIPS 协议中的灵活性。它们还需要制定和执行旨在使所有人都能获得药品的国内政策。它们需要在国内层面实现《多哈宣言》的目标。如果没有这样的政策和法律，那么该《宣言》在国际层面获得的成果并不能给病人带来真正的惠益。

换句话说，尽管近些年来，药品可获取性目标在国际层面已经有了很大的进展，但是现在国内的行动同样重要甚至更为重要，决策者应当集中出台政策和采取实际措施从而使贫穷的病人能够获得药品。

二、符合 TRIPS 协议的国内公共卫生措施

政府可以采取一系列措施促进可负担药品的可获取性，包括以下措施：

（一）进口药品

一国可以通过为一个企业或机构颁发强制许可来进口专利药品的仿制药，政府可以自由确定颁发强制许可的基础理由。进口的药品可以来自该药品未获得专利的国家，或者获得药品专利的国家（在这种情况下出口国也必须颁发强制许可）。申请人必须首先与专利权人进行获得自愿许可的协商（除却公共非商业使用、极端紧急状态或国家紧急状态的情形），如果协商失败，则可以颁发强制许可。但需要对专利权人支付足够的补偿费。

专利药品的仿制药也可以由政府以“公共非商业性使用”而进口。在这种“政府使用”程序下，不需要专利权人的事先同意或与专利权人的协商，但是需要支付足够的补偿费。如果进口药品是由政府使用，这种方法是很合适的。

还有“平行进口”，比如没有专利权人的同意而由一国进口和再销售已在平行专利下于出口国市场上合法销售的专利药品。这是一项非常重要的工具，可以促进可负担药品的可获取性，因为在不同的市场上药品的价格还是有很大差别的。TRIPS 协议第 6 条（权利穷竭）允许平行进口，《多哈宣言》确认了这一作法，它称每个 WTO 成员方都“能够自由地，不受干扰地建立其权利穷竭制度”。进口方不需要获得强制许可或给予专利权人补偿费。

（二）本国生产

如果药品在一国获得专利，该药品的仿制药可以由已经获得强制许可的本国企业在本国生产，在申请强制许可之前，申请者必须与专利权人协商以获得自愿许可，并且协商失败未取得这种许可。但是，如果强制许可是以公共非商业性使用、国内紧急状态或极端紧急状态、纠正反竞争行为而颁发，则这一要求不适用。但需要给予补偿。

如果是为了公共非商业性使用目的，政府也可以赋予公共或私营机构在未经专利权人同意下在本地生产专利药品的权利。但必须给予补偿。

（三）出口，包括出口至没有足够生产能力的国家

在强制许可和政府使用之下，专利药品仿制药的本国生产者可以将其产品的一部分用于出口。然而，TRIPS 协议第 31（f）条要求这样的生产应“主要用于国内市场的供应”，因此对可以用于出口的数量进行了限制。但当颁发强制许可是为了纠正反竞争行为时，这种限制就不适用。

出口数量的限制对没有生产能力的国家或没有足够生产能力的国家制造了问题，因为它们可能会发现由于潜在的出口国可以供应的数量受到限制因而很难进口所需要的药品。

《多哈宣言》承认这个问题有可能影响药品可获取性，并且授权 WTO 寻找一个“快速的解决方案”。在漫长的谈判之后，2003 年 8 月，WTO 总理事会通过了一个“临时解决方案”，作为对第 31（f）条的限制的过渡豁免方式，这样在强制许可下生产专利药品仿制药的国家可以不受出口数量限制将产品出口到合格的进口国。

然而，决议也要求希望利用豁免的进口国和出口国采取一些措施并满足一些条件。一些专家和非政府组织指出，这些措施和条件对于相关的公司和政府很难遵守。

“主席声明”下有一些额外要求与决议有关，比如这一制度应由于善良意愿而使用，而不应该追求商业政策目标，相关成员方可以就决

议如何实施，将该事项提交 WTO 的 TRIPS 理事会审议。

由于“豁免”及其适用条件只是一个“临时解决方案”，WTO 已经授权就这一问题寻找一个“永久性解决方案”。2005 年 12 月，WTO 总理事会对 TRIPS 协议作出了一些修正，基本上是 2003 年“临时解决方案”的重述。这个修正案只在有一定数量国家批准时才会生效。2007 年 1 月，批准国还没有达到这个数量，因此，2003 年 8 月的“临时解决方案”依然有效。

2007 年 10 月 28 日，中国政府批准了《修改 TRIPS 协议议定书》。2008 年 12 月 27 日，中国《专利法》第三次修改获得通过，并将于 2009 年 10 月 1 日起开始施行。新修改的《专利法》中有关专利实施强制许可部分也加入了 2003 年 8 月“临时解决方案”的相关内容。

三、运用 TRIPS 灵活性：最新经验

如果一个国家要达到目标并且遵守 TRIPS 协议中列明的原则，则该协议中灵活性的执行就很关键。TRIPS 协议第 7 条明确地表达了保护和执行知识产权目标为“促进技术革新、技术转让和技术传播，有利于生产者和技术知识使用者的相互利益，保护和实施的方式应有利于社会和经济福利，并有利于权利和义务的平衡”。

第 8 条（原则）承认知识产权权利人可能会有滥用权利的行为，不合理地限制贸易或反过来影响技术的国际性转让，政府可以采取与 TRIPS 协议相一致的“适当措施”防止这种行为的发生。它也承认政府可以采取必要的措施来保护公众的健康和营养，维护在对于其社会经济和技术发展来说至关重要的领域中的公众利益，所采取的这些措施与 TRIPS 协议的规定要相一致。

许多年来，甚至在 TRIPS 协议生效前，一些发达国家在很多情况下运用了强制许可。

相比之下，极少数发展中国家运用过 TRIPS 的灵活性。这其中有很多原因，比如，缺乏意识到或没有理解这些灵活性，政府部门缺乏与知识产权相关问题的法律专家（尤其是从发展的角度），有关 TRIPS 协

议灵活性的法律规定不适当或不充分，最后是来自发达国家政府和产业界的压力，特别是跨国制药公司。

这种施压的一个例子就是在2001年，39家制药公司起诉南非政府，因为南非政府修改法律（1997年第90号《药品及相关产品管理法》修正案），要将平行进口和强制许可的规定加入其中，从而增加对不太昂贵药品的可获取性。后来由于面临来自国内和国际的舆论批评，这些公司撤回了诉讼。

由于专利对价格的影响遭致批评，于是2001年通过了《多哈宣言》。正如前文所说，《宣言》承认“TRIPS协议不能也不应当妨碍成员国为维护公共健康而采取措施”，并确认“该协议能够也应当以一种有助于成员国维护公共健康的权利，特别是促进所有的人获得药品的权利的方式进行解释和实施。”

非常重要的是，《宣言》重申“WTO成员有权充分运用TRIPS协议中为此而给予的灵活性条款。”

两个重要而有影响的研究强调了TRIPS协议灵活性对发展中国家的至关重要性：

- “整合知识产权和发展政策”–知识产权委员会报告，英国（2002）；[1]和WHO知识产权、创新和公共卫生委员会（CIPIH）报告（2006）。[2]

两个委员会由国际知识产权、发展和公共卫生专家组成。

自从《多哈宣言》通过以来，尽管仍然面临着压力，更多的发展中国家行使了自己的权利，运用可以适用的灵活性来获取不太昂贵的药品。

下文有发展中国家使用TRIPS灵活性的一些例子。同时请参见附件1的强制许可官方文件。

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[1] www.iprcommission.org.报告中文版见 http://www.iprcommission.org/graphic/Chinese_Intro.htm

[2] http://www.who.int/intellectualproperty/documents/thereport/CHPublicHealthReport.pdf

美国和意大利的强制许可实践也将包括在这里。

（一）泰国

泰国有最有序的实施“政府使用”的体系。最近几年，政府意识到专利药品是昂贵和难以承受的，导致了国民没有足够途径获得。一个卫生部领导的政府委员会设立了，以确定在国家基本药品清单上的为了政府使用的药是必需的：

- 用以解决公共卫生问题，
- 紧急状态或极度紧急情形，
- 流行病或全国范围疾病暴发管理，
- 挽救生命。

该委员会研究专利产品仿制药替代的可行性、质量、价格。然后仿制药由政府药品组织（GPO）生产。

泰国专利法 1979 第 51 部分规定政府任何部、局或部门可以通过自己或其他人使用专利拥有者的权力“以服务于公众消费或为了生死攸关的国家防御，或为了自然资源或环境的保留与实现，或防止与减轻食品、药品或其它消费品的严重短缺或为了任何其他公共服务”。

2001 年政府建立了全民健康保障计划并开始本地化生产无专利的一线 ARV 组合制剂。2003 年开始了为有需要的所有泰国公民提供 ARV 治疗的第二个项目。

2005-2006 年发生了广泛的包括公众、法律专家甚至立法者和法官参与的针对超 TRIPS 条款被包括在拟议中的泰-美自由贸易协定的反对活动。当泰国军队获得国家政权时，双边谈判被搁置。

随着 ARV 的需求增加，2006 年 11 月，泰国卫生部颁布了“政府使用”形式的强制许可，由 GPO 本地生产依非伟仑。GPO 进口或本地生产依非伟仑总销售额的 0.5%作为使用费付给专利权人。2007 年有 100，000 艾滋病人接受了 ARV 治疗。

2007 年 1 月，“政府使用”被授权给 GPO 制造洛匹那韦 + 利托那韦固定组合制剂（二线 ARV）和氯吡格雷（治疗冠脉疾病）。这是发展中国家首次用于非 ARV 的强制许可。

泰国实施 TRIPS 灵活性引发了大跨国制药企业（如雅培、赛诺菲-安万特）和美国政府的巨大压力与威胁。然而泰国政府并未让步，且其做法启发了其它发展中国家。全球公众对泰国的支持也很有力。

2008 年 1 月，泰国卫生部宣布四个基本抗癌药物将被列入政府使用清单中。请参见附件 2 和 3 中泰国卫生部发布的两份解释政府为何需要使用强制许可的白皮书。

益处是明显的。依非伟仑的仿制药比专利产品价格降低了 87%。克力芝（洛匹那韦+利托那韦）降低了 67%。氯吡格雷降低了 98%，而抗癌药 Docetaxel 降低了 96%，来曲唑降低了 98%（见表 1）。对基本 ARVs 的获取性已经大大增加了。由于来自仿制药的竞争，专利药品的价格也降低了，不过前述这些药品的价格还是很高。

表 1　政府使用前后药品的价格比较

药品名称	价格（美元）			
	政府使用之前的专利药品	政府使用之后的专利药品	仿制药	费用/价格下降比例（%）
依非伟仑	58/月	24/月	7.5/月	87%
克力芝（洛匹那韦+利托那韦）	1，800/年	1，000/年	600/月	67%
氯吡格雷	3	1.3	0.06	98%
Docetaxel	900	450	37	96%
来曲唑	7	2.2	0.1	98%

来源：泰国卫生部 Suwit Wibulpolprasert 博士

（二）马来西亚

2003 年马来西亚成为亚洲第一个运用多哈宣言颁布“政府使用”许可的国家。此举是为了从印度公司 CIPLA 进口专利 ARV 的仿制药以便

在政府医院使用。

专利 ARV 是去羟基苷 100 毫克，25 毫克片剂（专利持有人：施贵宝公司）；齐多夫定 100 毫克胶囊，拉米夫定 150 毫克 + 齐多夫定 300 毫克固定组合片剂（专利持有人：葛兰素公司）

授权期限始于 2003 年 11 月 1 日，为期 2 年，用以进口齐多夫定、去羟基苷和双汰芝，动议由卫生部提出，按照专利法"政府使用"法律条文，获得内阁支持，许可颁给国内贸易和消费者事务部。

作为此 "政府使用"的结果，卫生部治疗每个病人的每月花费从 315 美元降到了 58 美元（约 81%）见下表 2。

大大降低的费用鼓励卫生部为所有需要者提供了免费治疗。以前，免费治疗仅提供给经选择的病人类型。另外，根据卫生部的信息，可以在政府医院及诊所治疗的病人从 1，500 增加到了 4，000。

作为运用"政府使用"权力的结果，专利权人降低了自己的价格也导致了治疗费用的显著下降，如下表 2。

表 2　马来西亚"政府使用"
许可进口仿制 ARV 后病人每月治疗费用比较

治疗方案	2001 年专利 ARV 价格(USD)	2004 年专利 ARV 价格(USD)	2004 年仿制 ARV 价格 (USD)	费用下降百分比
司他夫定+去羟基苷+奈韦拉平	261.44	197.10	45.32	83%
齐多夫定，拉米夫定+依非伟仑组合	362.63	136.34	115.14	68%

来源：马来西亚卫生部

卫生部提议给专利持有人每年实际发货量价值的 4%作为报酬。专利持有人并没有显示要求这个补偿的兴趣，据报道是不想树此先例。

一个本地制造商基于政府医院使用拉米夫定（其它两种组分为非专利品）的自愿许可，现正在生产 3 合 1 的固定组合制剂。因为这可以

为所有病人降低更多价格，特别是二线 ARV 克力芝。

（三）印度尼西亚

2004 年 10 月 5 日颁布了 2004 第 27 号总统令 -“法规关于‘政府利用’专利机制”，这是根据“努力控制艾滋病流行的紧急需要”。

“关于‘政府利用’ARV 专利”的 2004 第 83 号总统令授权卫生部根据国家食品药品管理机构负责人推荐，指定一家药厂为政府利益而使用专利。两个 ARV 是奈韦拉平（7 年）和拉米夫定（8 年），使用期覆盖剩余的专利保护期。

总统令也设定了 ARV 纯销售额的 0.5% 作为专利持有人的补偿。

需要 ARV 的病人可以从政府医院得到免费或部分补贴的药品。由授权仿制药制造商 Kimia Farma 生产的一线固定组合制剂（拉米夫定，齐多夫定+ 依非伟仑），每月每治疗方案费用为 38 美元。政府每月提供 20 美元补贴，所以病人只需要为每月每治疗方案付 18 美元。

作为比较，葛兰素公司生产的拉米夫定是每 60 片 290 美元，勃林殷格翰的奈韦拉平是每 60 片 96 美元。

根据印度尼西亚大学医学系艾滋病工作组的信息，虽然市场上有仿制药，ARV 价格却没有显著下降。大学项目中治疗的几乎所有 2，000 病人已转为用国产仿制药。

2007 年初，印尼政府颁布了 2007 第 6 号总统令“修订 2004 第 83 号总统令‘政府使用’ARV 专利”。这是对需要“增加‘政府使用’ARV 专利数量以增加 ARV 获得途径”的认可。

总统令在以前清单上 2 种 ARV 外增加了依非伟仑。专利持有人是默克公司，专利使用期直到 2013 年 8 月 7 日专利到期。

2012 年 9 月 3 日，印尼总统苏西洛·班邦·尤多约诺博士签发了一份法令，对七种治疗艾滋病和乙型肝炎的药物授予政府使用专利。这些

药物分别是：依非伟仑、阿巴卡韦、去羟肌苷、洛匹那韦+利托那韦组合、替诺福韦、替诺福韦+恩曲他滨以及替诺福韦+恩曲他滨+依非伟仑。

法令授权卫生部指定制药公司为政府并代表政府开发专利。授权在每项专利的有效期截止前都有效。印尼给专利持有人的使用费费率为0.5%。

专利持有人包括默克、葛兰素史克、百时美施贵宝、雅培和吉利德。10月19日的《雅加达邮报》援引印尼卫生部传染病控制主任H.M.Subun所言："我们将保证提供优质、安全和有效的抗逆转录病毒和抗病毒药物。"

如上所述，印尼早在2004年就授权政府使用专利（拉米夫定和奈韦拉平），2007年又再一次作出授权（依非伟仑、拉米夫定和奈韦拉平）。2012年新的法令称，为了在印尼控制艾滋病和乙型肝炎的紧急需要，"有必要持续并扩大可及性政策从而提供仍受专利保护的抗病毒和抗逆转录药物的可及性。" 法令称之前对三种旧的治疗艾滋病药物专利的政府使用法令"不再充分"。新法令代替了之前的法令再次对依非伟仑作出许可，并且在治疗方案中还加了六种药物。如果能完整地实施，这项措施将带来大规模的仿制药竞争并可以潜在地节省大量成本。

根据美国的国际生态知识（KEI）分析，新的法令可能代表着自世界贸易组织（WTO）《与贸易有关的知识产权协定（TRIPS）》缔结以来一个国家最大范围地单独使用药物专利许可权。这是印尼大幅度扩大更新更合适抗病毒和抗逆转录治疗可及性所作努力的一部分，也是帮助拯救艾滋病和乙型肝炎患者/感染者生命和改善他们生活迈出的重要一步。印尼的行动为其他国家树立了一个强有力的榜样，也为全球公共卫生奠定了一个重要先例。

许可药物表

活性物质	专利持有人	专利号	专利有效期
依非伟仑	默克公司	ID 0005812	专利有效期至 2013 年 8 月 7 日
阿巴卡韦	葛兰素集团有限公司	ID 0011367	专利有效期至 2018 年 5 月 14 日
去羟肌苷	百时美施贵宝公司	ID 0010163	专利有效期至 2018 年 8 月 6 日
洛匹那韦/利托那韦组合	雅培公司	ID 0023461	专利有效期至 2018 年 8 月 23 日
替诺福韦	吉利德科学公司	ID 0007658	专利有效期至 2018 年 7 月 23 日
替诺福韦+恩曲他滨组合 替诺福韦+恩曲他滨+依非伟仑	吉利德科学公司	ID P0029476	专利有效期至 2024 年 11 月 3 日

来源：http://www.citizen.org/actions-indonesia

（四）巴西[3]

巴西总统，Luiz Inacio Lula da Silva，2007 年 5 月 4 日签署了一项对抗逆转录病毒药物依非伟仑的强制许可制裁性法令，依非伟仑。该抗逆转录病毒药物被宣布为 2007 年 4 月 24 日卫生部长签发条例中的“公共利益”。巴西已表示，其决定是在“绝对遵守国际要求和巴西法律”。

专利持有人默克公司，被给予时间，以便对该抗逆转录病毒药物价格作出一项新的建议。默克公司提出它可以当前价格（每片 US$1.59）的 30%提供该药物，（即每片 US$1.11 元），但巴西卫生部的报告说，它可以在其他地方取得该药品为每片 US$0.45。

[3] Summary by Sangeeta Shashikant, TWN IP Information dated 8 May 2007. For the official Brazilian government decree see http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717

依非伟仑在巴西是最常用的治疗艾滋病的进口抗逆转录病毒药物。目前，有 38%的艾滋病患者用依非伟仑作为他们治疗计划的一部分。据估计，今年年底，巴西的 20 万艾滋病患者中的 75000 人会用此抗逆转录病毒药物。

目前默克公司在巴西制定的价格使每名病人年花费相当于 US$580，即为 2007 年 4，290 万美元的预算花费。仿制药产品每名病人的年费用在 US$163.22 和 US$166.36 之间。基于对这些数字，在强制许可下，在 2007 年将削减开支约 3000 万美元。当 2012 年依非伟仑专利失效时，估计可以节省 23.68 亿美元的花费。

2007 年 5 月 4 日，在巴西国家性病和艾滋病项目网站上（www.aids.gov.br）发布的新闻给出以下与制药公司在其他药物谈判的背景：

“在 2001 年 8 月，当时的卫生部长，José Serra，要求强制许可奈非那韦（罗氏公司制造）的专利。决定在此后 9 个月与该公司谈判。然而，在同一天这位部长又宣布，这一进程已中断。因为罗氏公司同意将药物的价格降低 40%。”

“在 2003 年 12 月，卫生部长 Humberto Costa 宣布，可能采用强制许可以便在巴西生产奈非那韦。Humberto Costa 当时 解释，他希望与罗氏公司进行谈判，但如有需要将颁布强制许可法令，2004 年 1 月，卫生部长成功地获得 5 个药品减价：奈非那韦，洛匹那韦，依非伟仑，替诺福韦和阿扎那韦。这项协议，使这些抗逆转录病毒药物比以前支付的价格下降了 37%”。

“2005 年 6 月，总统 Luiz Inácio Lula da Silva，以及卫生部长 Humberto Costa，签署了一项关于雅培公司制造的抗逆转录病毒药物克立芝（洛匹那韦+利托那韦）关系到公众利益的声明。同年 7 月，卫生部长发表与雅培谈判结果的声明，确认药品降低价格时间为六年，并可获得克立芝的新剂型（为 Meltrex）和转让制造洛匹那韦+利托那韦的技术。雅培同意减少克立芝胶囊的单位价格，从每个 US$1.17 美元减到 US$0.63，意味着从 2006 年 3 月生效起，在 2006 年至 2011 年间，

可节省 33.95 亿美元。”

（五）津巴布韦

在 2002 年，基于全国流行的艾滋病毒感染/艾滋病影响了国家，司法，法律和议会事务部长签发了一个通知，“紧急状态（艾滋病毒感染/艾滋病）的声明”，为期 6 个月。

该通知的用意是允许国家或由部长授权的人，（a）使用任何专利药物包括任何抗逆转录病毒药物和（b）进口任何用于治疗艾滋病毒感染/艾滋病或相关病症的非专利药物。

紧急状态期以 2003 年 32 号法令延长了 5 年，即从 2003 年 1 月 1 日至 2008 年 12 月 31 日。在此期间，国家或由司法部长授权的任何人可以制造或使用专利药品或进口任何仿制药，用于治疗艾滋病毒感染/艾滋病或相关疾病。

Varichem 制药（私人）有限公司，津巴布韦的仿制药公司，根据专利法第 34 条申请制造、使用或运用专利办公室公开的发明信息，以为国家服务。

在此申请后，司法、法律和议会事务部长在 2003 年 4 月授权 Varichem“生产抗逆转录病毒药物或艾滋病毒感染/艾滋病相关药品，生产的药物将供应国有医疗机构 3 个季度，”这项许可还指明药品价格将根据由部长确定的价格控制机制固定。

据 Varichem 代表说，在 2003 年 10 月该公司生产了第一个抗逆转录病毒药物，它在市场上有 7 种抗逆转录病毒药物即双汰芝，奈韦拉平（200 片剂），Stalanev - 40（固定剂量组合制剂，包括司他夫定 40 mg，拉米夫定 150 mg 和奈韦拉平 200 毫克），Stalanev - 30（司他夫定 30 mg，拉米夫定 150 mg 和奈韦拉平 200 毫克），司他夫定（30 mg 胶囊），司他夫定（40 mg 胶囊）和拉米夫定（150 mg 片剂）。

（六）加纳

在 2005 年 10 月，加纳政府颁布了一份政府使用的命令，进口（从选定的印度仿制药公司）经选择的在加纳有专利的抗逆转录病毒仿制

药。根据卫生部所述，这些艾滋病毒感染/艾滋病药物仅用于治疗病人，供政府使用，没有商业用途。据官方消息人士透露，抗逆转录病毒药物治疗成本下降了近 50%，年治疗费用从 US$495 美元降到 US$235。

（七）美国[4]

联邦法典 1498 第 28 条有关政府使用的案例

联邦法典 1498 第 28 条 是关于由或为了政府使用专利或版权的法律。根据这项法律，美国政府并不需要寻求专利许可或进行谈判以使用一个专利或版权。任何联邦雇员可以使用或授权使用专利或版权。权利所有者有权获得补偿，但不能责成政府或政府授权的第三方阻止使用。任何被联邦政府授权的承包商，分包商，个人，商号，或公司，使用专利或版权视为联邦政府使用，不能被起诉侵权。

2001 年，当时的卫生和人类服务部（DHHS）部长 Tommy Thompson 援引联邦法典 1498 第 28 条威胁授权进口环丙沙星仿制药，以便进行药品储存应对可能的炭疽攻击。[5]

在 2005 年 11 月的一个国会听证会上，当时 DHHS 部长 Michael Levitt 在众议院作证，他已有效地要求达菲的专利拥有者（罗氏/吉利德）为此产品投资于美国的制造设施，，使美国政府面对禽流感大流行可以获得达菲。[6]

涉及并购的案例回顾

2002 年，美国联邦贸易委员会（FTC）下令强制交叉许可 Immunex 公司的肿瘤坏死因子（“TNF”）专利给 Serono 公司，[7]包括“TNFbp-I 产品、糖基化和非糖基化片段、衍生物和类似物在美国的研究，开发，制造，使用，进口，出口，分配和销售的自由运作。”注意许可出口，

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[4] Extracted from Love, J “Recent examples of the use of compulsory licenses on patents”, Knowledge Ecology International Research Note 2007:2, pages 3-4.

[5] For more information: http://www.cptech.org/ip/health/cl/cipro/

[6] See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, http:// www. cptech. org/ip/ health/ tamiflu/hearingexcerpts11082005.html

[7] For more information: http://www.ftc.gov/opa/2002/07/amgen.htm

可见于 TRIPS 第 31.k 款。在这个案例，强制交叉许可允许了瑞士公司与美国专利拥有者的竞争。

2005 年，联邦贸易委员会下令强制许可 Guidant 公司药物洗脱支架（DES）的 RX 传输体系的知识产权，作为无论强生公司或波士顿科学公司收购 Guidant 的条件。[8] 最终赢得 Guidant 竞标收购的波士顿科学公司被要求许可 DES 专利给一个潜在的竞标者，雅培。

（八）意大利[9]

默克抗生素（亚胺培南西司他丁）专利

2005 年 2 月 23 日，意大利竞争管理局（Autorità garante della concorrenza e del mercato –AGCM）开始了对两个大制药公司-葛兰素公司和默克公司滥用支配地位，拒绝给与原料药专利许可的调查，（案件 A363 和 A364）。

2005 年 6 月 21 日，AGCM 下令颁布对默克公司专利抗生素活性成分亚胺培南西司他丁的强制许可。

葛兰素治疗偏头痛的专利药物

2006 年 2 月 8 日，AGCM 结束对葛兰素集团的一个深入调查，因为葛兰素拒绝给予一个化学公司，Fabbrica Italiana Sintetici SPA（FIS），用于在意大利制造一个治疗偏头痛的药物活性成分，琥珀酸舒马普坦的专利许可。

根据 AGCM 新闻稿，“为了弥补先前的拒绝发放许可，葛兰素史克给予 FIS 专利许可，但设定条件，如因为原来的拒绝耽误的时间也算作许可期限内。这些条件也包括给予一些额外的过程专利许可，葛兰素允许 FIS 节省否则须研究和测试一个有效率的琥珀酸舒马曲坦制造过程的时间。 FIS 从而使给仿制药制造商提供活性成分的时间提前到

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[8] For more information: http://www.ftc.gov/opa/2006/04/bostonscigui.htm

[9] 摘自 Love, J “Recent examples of the use of compulsory licenses on patents”, Knowledge Ecology International Research Note 2007:2, pages 10-11

如同葛兰素从来没有拒绝原专利许可请求”。[10]

AGCM 为大幅度削减药品价格，避免延误仿制药品进入市场，铺平道路。

FIS 开始使用强制许可完全是为出口市场，供应仿制药公司以在意大利以外的市场（如西班牙）销售产品，那里的专利已经过期。这样做是在 WTO 2003 年 8 月 30 日针对在强制许可下制造的供出口药品的决议框架外，对此西班牙和其他欧盟成员国已经作为进口国“退出”。部分可能的是因为对纠正反竞争行为而发出的强制许可，TRIPS 协议免除了所有对出口的限制。

默克公司治疗前列腺和男性秃顶的专利药物

2007 年 3 月 21 日，AGCM 要求默克“给予在意大利在 2009 年补充保护证书到期前两年制造和销售非那司提（Finasteride）活性成分和和相关仿制药的免费专利许可”。[11]非那司提是最初以 proscar 和 propecia 商品名下销售的药品的活性成分。它用来治疗前列腺肥大，前列腺癌症和男性秃顶。默克的免专利费强制许可是它早些时候拒绝发放专利许可给原料药意大利制造的补救措施，。再次，许可是预期出口至“其它欧洲国家”。

（九）印度[12]

2012 年 3 月 12 日，印度专利、设计和商标管理总局对治疗癌症药

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[10] AGCM. 21 February 2006. PRESS RELEASE: Pharmaceuticals: Antitrust says Glaxo has made amends and abuse of dominant position discontinued Granting of licence opens way for manufacture of generic migraine drugs. PROCEEDING reference n. A363, case GLAXO-PRINCIPI ATTIVI.

[11] 26 March 2007. Press Release, A364 - Merck - Active Ingredients (Conclusion Of Investigation): Antitrust Authority Rules Merck Must Grant Free Licenses For The Active Ingredient Finasteride. The Authority accepts and renders obligatory a commitment presented by the companies Merck & Co. Inc. and Merck Sharp & Dohme (Italia) in order to conclude the investigation launched in February 2005 into possible abuse of a dominant position. Expected price reductions for the drug to benefit consumers and the National Health System. http:// www. agcm.it/ agcm_eng/ COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/28653b373e56772ac12572ab003a4d68

[12] 来源：http://keionline.org/node/1384;

http://twn.my/title2/intellectual_property/info.service/2012/ipr.info.121004.htm

物甲苯磺酸索拉菲尼/多吉美发布了一项强制许可，该药物的专利由德国拜耳公司持有。

拜耳的索拉菲尼在印度的价格是每年 69,000 美元，这是印度 2012 年预计国民人均收入的 41 倍。这项强制许可措施可以将治疗肝肾癌症药物的价格从每月 5,200 美元降到每月 160 美元（仿制药的价格），相当于专利药价格的 3%。

NATCO 制药公司是一家印度仿制药公司，它根据印度《专利法》第 84 节规定的三个理由申请强制许可，这三个理由在 NATCO 诉拜耳一案的裁定中都得到了支持，该裁定以联合国开发计划署 2001 年专利权使用费指南中规定的最高点授予 6%的专利权使用费。基于当产品并非“合理可负担”时，专利垄断权是有限的，管理总局很早就在审查是否符合这一印度专利法中驳回了拜耳的一些申辩理由。

拜耳在定价上的主要申辩理由是它对低收入患者的折扣计划以及 CIPLA（另一家印度仿制药生产商）以更低的价格出售“侵权”产品这一事实。它认为高昂的价格是基于高额的研发成本，却没有提供用于研究的实际支出的任何细节。事实上，索拉菲尼得到了美国孤儿药品税收抵免的补贴，并且它是拜耳和 Onyx 制药公司共同开发的。

然而，授予强制许可的决定很有限。只有 NATCO 可以在这项强制许可下进行生产。NATCO 也不能进口该药物以满足印度市场的需要。这假设了 NATCO 可以完全满足印度的需求。

拜耳将对这一决定提出上诉，该案有可能会诉至印度最高法院。但是，印度政府向保护其公众免受拯救生命的专利药物高昂价格之苦迈出了重要的第一步。

这一决定作出之后，瑞士制药巨头罗氏公司也宣布在不久的将来就它的两种治疗癌症药物给与更低廉的价格，且以本地品牌形式销售。但是，随着美国商务部部长约翰·布莱森向印度商务部长状告印度专利管理局发布的强制许可决定，称这个决定是“对国际专利制度的稀释”，发达国家也开始施加政治压力。

因此，第三世界网络与无国界医生于 2012 年 4 月 2 日组织了一个研讨会重点讨论这个案子，并且推动采取更多行动扩大拯救生命药物

的可及性。律师 Rajeshwari Hariharan 女士在印度专利管理总局代理 NATCO 的案子，她非常详尽地描述了 NATCO 在甲苯磺酸索拉菲尼的强制许可申请中运用的策略和具体主张。她描述说这是一个对 NATCO 而言非常理想的案子，因为他们可以低成本地生产药物并低价出售。因此 NATCO 决定将这个案子作为申请强制许可的一次测试。她描述了他们在申请过程中必须明确的经济、社会和法律的各种主张。她也对 NATCO 未来的规划以及对具备这种强制许可申请可能性的其他药物给出了清晰的看法。

这场讨论由来自研究机构、公民社会组织、印度小型制药公司、联合国艾滋病规划署、印度医学研究理事会以及其他机构的 40 多名参会者参加。

（十）厄瓜多尔[13]

2012 年 11 月 12 日，厄瓜多尔继 2009 年第一次对利托那韦/洛匹那韦发布强制许可之后又发布了本国的第二次强制许可，这次是针对阿巴卡韦/拉米夫定。

厄瓜多尔知识产权研究所的一份新闻稿称，强制许可是通过帮助国家实现联合国千年发展目标以扩大药物可及性的国际贸易规则中不可或缺的一部分。一盒 30 片装的阿巴卡韦/拉米夫定在厄瓜多尔的零售价是每月 753 美元，一年期疗程为 9,036 美元。在美国，一盒 30 片装的阿巴卡韦/拉米夫定是 745 美元或每片 24.83 美元。

厄瓜多尔将这项强制许可授予厄瓜多尔生产商 Acroxmax。通过这项强制许可，厄瓜多尔努力将阿巴卡韦/拉米夫定的成本降低 75%。它参考 2005 年世界卫生组织/联合国开发计划署的分级计费法（Tiered Royalty Method, TRM）来确定专利权使用费费率，每颗胶囊为 11.7 美分。根据美国的国际生态知识（Knowledge Ecology International，KEI）的分析，这参照了美国制药业专利权使用费的平均水平。按照美国的价格，假设专利权使用费平均为 5%，然后扣除每颗胶囊的使用费，从而反映出相对人均名义收入的差异。

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[13] 来源：http://www.citizen.org/actions-ecuador

四、双边自由贸易协定 (FTAs) 对实施与公共健康有关的 TRIPS 协议灵活性的影响

（一）在多边背景下增强对知识产权问题的意识

在贸易协定中引入知识产权问题并制定有约束力的规则是很有争议的，TRIPS 协议被放入 WTO 之后仍然这样。自那以后，许多经济学家，从约瑟夫.斯蒂格利茨（Joseph Stiglitz）到贾格迪什.巴格沃蒂（Jagdish Bhagwati），都谴责在 WTO 中引入知识产权问题和 TRIPS 协议。人们越来越多地意识到 TRIPS 协议中知识产权的高标准对于发展中国家的发展需求很不适合。特别是，世界银行贸易研究部前负责人迈克尔.芬格（Michael Finger）估计发展中国家履行 TRIPS 协议义务的成本高达每年 600 亿美元，这远远抵消了它们期待可能因其它 WTO 协议下扩大的农业和纺织品市场准入而获得的利益。

现在发展中国家采取了一些行动以澄清 TRIPS 协议中的某些问题或者作出修改从而减少对发展的负面影响。比如，《多哈宣言》明确了发展中国家可以利用一些灵活性，如强制许可，来应对专利权人的垄断特权。

（发展中国家也在试图修改 TRIPS 协议从而解决“生物剽窃”问题，它们要求涉及生物资源的专利申请要披露资源的来源国以及与这些国家惠益分享安排的证据。）

当 WTO 的谈判者更多地意识到知识产权对发展的影响时，发达国家已经试图通过另一个论坛即世界知识产权组织（WIPO）在全球范围内引入更高的知识产权标准。然而，许多发展中国家现在已经采取新一轮行动在 WIPO 中建立一个“发展议程”。它们也试图抵制以更高的标准协调专利法和版权法。

（二）双边自由贸易协定侵蚀 TRIPS 灵活性的危险

因此，一些发达国家试图利用自由贸易协定这一论坛：（1）取消或减少 TRIPS 协议的灵活性；（2）在发展中国家确立更高的知识产权标准。因而，知识产权是双边自由贸易协定所涉及的一项主要内容。在这一领域，像美国和日本这样的国家更是不遗余力地扩大自己超出

TRIPS 协议的利益。自由贸易协定威胁到了与专利和药品可及性以及包括生物多样性在内的知识产权其它方面相关的 TRIPS 协议灵活性的运用。

在知识产权和公共健康方面，FTAs 会造成严重影响。运用 TRIPS 协议灵活性如强制许可和政府使用的权利可能会受到侵蚀，甚至通过 FTAs 中的一些规则而被取消。因此，这也将影响到 FTA 发展中签署国实施《多哈宣言》的能力，《多哈宣言》明确了促进药品可及性政策的可行的灵活性。

美国与一些国家或国家集团签署的双边 FTAs 正在限制 WTO 中 TRIPS 协议所允许的灵活性或相关措施。这造成的后果是 FTA 的发展中国家伙伴发现采取象强制许可或政府使用这样的措施为患者提供廉价仿制药会变得更困难或根本不可能。这样的情况（见无国界医生报告：《药品可及性在全球面临威胁》）包括：

（1）数据专属权. WTO 并没有要求“数据专属权” - 即专利权人向药品管理部门提交的数据（基于用药安全获得上市许可）不能被其他申请人用来作为药品管理部门审批程序的一部分。因此，仿制药生产者（获得允许，比如通过强制许可，销售或生产专利药品的仿制药）在从药品管理部门寻求获得安全性许可时可以利用这一数据。然而，在双边 FTAs 中，美国想要确立或扩大对原研药企业提供的实验数据的“专属性权利”以防止仿制药企业注册等效的仿制药，从而阻止或使得强制许可难以起作用，并有效地抑制仿制药的供应。美国与新加坡签订的 FTA 中就包含了这种限制。

（2）延长专利保护期. 药品专利在大多数国家从申请日起持续 20 年；这也是 WTO 的要求。但是，美国正在为由于一国的药品管理机构或专利局因审查和批准申请而使用的任何“不合理”时间为制药企业寻求补偿。专利的保护期将由于“不合理时间”而得到延长。美国与中美洲国家签订的 FTA（CAFTA）中就规定了这样的延期措施。

（3）专利的“常绿化”. 当专利过期之后制药企业会试图通过就同样产品的“新用途”申请新的专利从而对专利进行更新。在 WTO 规

则下，成员方没有义务为现有物质的新用途授予专利。美国想要在 FTA 中作相应的规定，允许制药企业为产品的每一种“新用途”申请新的专利，从而使原始专利保护在到期后仍然得以继续。美国与摩洛哥签订的 FTA 中就有这样的条款。

（4）限制强制许可的理由。TRIPS 协议允许国家颁布强制许可并且没有对运用强制许可的条件作出限制，《多哈宣言》确认了国家“有决定授予强制许可理由的自由”。然而，美国却寻求对药品颁发强制许可的情况作出限制。例如，美国与新加坡签订的 FTA 只允许为纠正专利权人的反竞争行为、为了公共非商业目的以及在国家紧急状态或极端紧急状态下才可颁发强制许可。

（三）泰国人权委员会的报告

2007 年 1 月，泰国国家人权委员会发布了一份关于泰国正在与美国谈判的 FTA 的人权评估报告（草案）。

这份报告认为，这样一个协定将会侵犯泰国人民的人权，并且影响到国家主权，因此，除非对协定的影响作全面的审查，否则谈判不应该重启。（报告具体内容，见 Smith（2007））。

委员会的发现来自对美国提出的知识产权相关规定所作的人权评估以及基于美国所签署的其它双边协定文本中 FTA 的其它章节规定。

委员会认为“FTA 就象冲击了无防备海岸的海啸。”

在对知识产权规定的考察中，委员会集中在公共健康和农民权利所受到的影响上。委员会回顾了美国对泰国施压要求泰国提高知识产权保护以及学术界、公共卫生部门官员和非政府组织发起抗议的过程。

报告也解释了美国提出的要求超越了 TRIPS 协议的规定。这些“超 TRIPS”条款包括：植物、动物和治疗方法专利、专利权保护期超过 TRIPS 协议要求的 20 年、数据专属权、专利状态与药品注册的联系、禁止专利授予前异议、运用强制许可的限制。最后两项（如授予前异议和强制许可）最近已在泰国成功地运用，保证了对治疗艾滋病药品

的可获取性。

委员会着重指出了在泰国品牌/原研药的价格可能比仿制药高出10倍的研究发现。它认为，市场垄断的影响造成药品费用太高或者超过了人们的购买能力。

“首先，预计费用的增加超过 1，000 亿泰铢，超出了每年公共卫生的预算，必然会摧毁管理泰国卫生体系的任何努力尝试，特别是健康保险制度…在最后的分析中，泰国人无法获得药品，引发无数公共健康和社会问题…”

“这样做会损害普遍卫生保健体系以及很受欢迎的健康保险制度，破坏泰国人在医药领域发展自身潜力，自力更生以合理价格制造和销售高质量药品的能力。”

报告中委员会提出如下建议：

● 社会所有部门都应该参与到 FTA 的谈判过程中来，这一事项必须通过国会。

● 目前泰国应该推迟谈判从而能够对重要议题进行仔细审查。在当前临时政府执政的一年期间，与每个国家的 FTA 谈判都应该搁置，因为 FTAs 的谈判和签署从长远来看对泰国具有法律约束力。

● 在与药品和公共卫生服务相关的事项上，政府必须坚持病人和消费者权利原则以及在药品和公共健康方面坚持自力更生。如果美国要求对卫生条件、药品可获取性以及公共卫生服务施加影响，必须予以拒绝，而无需与美国所提供的利益作比较。

● 因为每个人都有获得健康的基本权利，在双边贸易谈判中不应该考虑与药品和公共卫生服务有关的知识产权问题。正如美国不同意将农业补贴放入议程中一样。

五、结论

专利可以并且确实经常影响到病人（特别是穷人）获取药品，TRIPS 协议也确实影响到 WTO 发展中国家成员按照自己的选择制定药品专利政策的空间。

尽管存在这些问题，但是为了促进所有人的药品可获取性目标，发

展中国家可以而且应该充分利用 TRIPS 协议所允许的措施。

为了行使“充分使用”TRIPS 协议灵活性（《多哈宣言》的措辞）的权利，发展中国家可以研究适合自己的政策方案并且制定合适的法律和采取切实的措施。长期来看，为了扩展现有的灵活性从而满足病人和消费者的需求，修改 TRIPS 协议也是可能的。由于百万人的生命悬于一线，因此短期和长期任务都非常紧迫。以上最新的国家经验表明，发展中国家完全可以利用 TRIPS 的灵活性从而扩大其国民对药品的获取能力。

附录：强制许可的最新经验

国家	强制许可的种类	理由	“充分的补偿”
马来西亚	强制许可给予本国公司用于进口供公立医院使用的药物	政府使用	提供4%给专利权人
莫桑比克	强制许可给 Pharco Mocambique Lda 用于本国生产	国家紧急状态或极端紧急状态	不超过销售额的2%
赞比亚	强制许可给 Pharco Ltd 用于本国生产	国家紧急状态或极端紧急状态	不超过产品交易总额的2.5%
印度尼西亚	许可给卫生部指定的制药厂作为专利实施人	政府使用	抗病毒和抗逆转录病毒药物净销售额的0.5%作为补偿费给专利权人
津巴布韦	强制许可给 Varichem 实施专利	紧急状态	
泰国	强制许可给政府制药机构用于生产依非伟仑	政府使用	仿制药销售价的2%给专利权人
加纳	强制许可用于进口 ARVs	政府使用	
巴西	强制许可用于制造依非伟仑	政府使用	
美国	强制许可 Immunex 公司的肿瘤坏死因子专利给瑞士公司用于研究、制造并在美国销售的产品（也允许出口）；对于药物涂层支架接受传送系统的知识产权强制许可	纠正反竞争行为	
意大利	强制许可用以生产抗生素中使用的活性成分亚胺培南西司他丁、用于生产治疗偏头痛药的琥珀酸舒马普坦、用于治疗前列腺肥大或前列腺癌和男性脱发产品的非那司提	纠正反竞争行为	
印度	拜耳公司甲苯磺酸索拉非尼专利许可给印度公司 Nacto	无法满足合理公共要求，且缺乏本地的运作努力以满足要求	
厄瓜多尔	许可给指定的制药厂	增加药品可及性，使国家达到联合国千年发展目标	11.7 美分/粒

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RECENT EXAMPLES IN DEVELOPING COUNTRIES OF COMPULSORY LICENSE, "GOVERNMENT USE ORDERS" AND OTHER MEASURES TO PROMOTE ACCESS TO MEDICINES

This dossier is compiled by the Third World Network. Most of the materials were made available by Consumer Project on Technology and is on its website www.cptech.org or www.keionline.org

GHANA

In case of reply the Number
And the date of this
Letter should be quoted

My Ref. No. SD-110/SF.3 Vol.

Your Ref. No....

MINISTRY OF HEALTH
P O BOX MB-44
ACCRA

26 October 2005

REPUBLIC OF GHANA

THE MANAGING DIRECTOR
IDA ARV PROCUREMENT SERVICES BV
P.O. BOX 37348
1030 AH AMSTERDAM
THE NETHERLANDS

Dear Sir,

NOTIFICATION OF EMERGENCY AND ISSUANCE OF GOVERNMENT USE LICENSE

The Minister of Health of Ghana has carefully considered the relevant WTO legal texts, being the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, regarding the patent situation of HIV/AIDS medicines and the procurement thereof within the framework of the national HIV/AIDS programme and hereby notifies you that:

Ghana as a Member of WTO has declared an emergency situation with regards to HIV/AIDS and has issued a government use license for importation into Ghana of generic HIV/AIDS medicines in accordance with national law.

The HIV/AIDS medicine will be used to treat people with HIV/AIDS without any commercial purpose and will be for government use only. The Minister of Health hereby suggests that measures be taken to speed up supply of the aforesaid medical drugs in order to continue a comprehensive treatment AIDS programme in Ghana.

Yours faithfully,

MAJOR COURAGE E. K. QUASHIGAH (RTD)
HON. MINISTER OF HEALTH

MOZAMBIQUE

On April 5, 2004, Mozambique's Deputy Minister of Industry and Commerce issued a compulsory license for patent rights to lamivudine, stavudine and nevirapine. The license was granted to Pharco Moçambique Lda, a local producer that plans on manufacturing the antiretrovirals as a fixed-dose combination. Royalties are not to exceed 2% of sales.

Source: www.cptech.org

REPÚBLICA DE MOÇAMBIQUE

MINISTÉRIO DA INDUSTRIA E COMERCIO
DIRECÇÃO NACIONALDA INDUSTRIA

A
PHARCO MOCAMBIQUE, LDA
MAPUTO

REF/GDNAL/DNI/MIC/04 Maputo, 29 de Margo de 2004

Assunto: LICENCA COMPULSIVA

Pela presente, se informa que o pedido de V.Exa de 29 de Janeiro do corrente, para a emissão de uma Licenqa Compulsiva para a produqiio de anti-retrovirais em Moqambique, mereceu uma apreciaqiio favoravel pelo que se emitiu a referida licença que vai em anexo.

Cordiais saudações

A Directora Nacional Adjunta

Olga Massango Gomes

REPUBLICA DE MOÇAMBIQUE

MINISTÉRIO DA INDUSTRIA E COMÉRCIO
Gabinete do Ministro

LICENÇA COMPULSIVA N°. 01/MIC/04

O Governo de Mogambique, consciente de que a pandemia do HIV/SIDA constitui uma séria ameaga no esforgo nacional de combate a fome, doenga, subdesenvolvimento e miséria e,

considerando que

os elevados niveis de morbilidade e mortalidade colocaram Mogambique entre os dez paises africanos mais assolados por este tipo de doenga. As estimativas conhecidas siio as de que no final de 2002 mais de 1,5 milhdes de moqambicanos foram infectados pelo HIV/SIDA, dos quais 100.000 padeciam já das manifestaqdes da doenga. O numero de mortes estaja acima dos 200.000 individuos e cerca de 360.000 crianqas siio órfãs devido a esta pandemia,

e que

apesar da multiplicação e diversificação de vigorosas campanhas de prevenção o alastramento do virus esta a aumentar, como e demonstrado pelo crescimento do numero de casos de infectados,

considerando ainda que

ja existem farmacos anti-retrovirais que prolongam a vida dos infectados com o HIV/SIDA, e que no entanto, até hoje, os detentores das patentes internacionais niio permitiram a acessibilidade desses farmacos, a preqos competitivos, a maioria do povo moqambicano,

e por essa razão

a 14 de Novembro de 2001 a Organização Mundial do Comercio declarou o direito a cada Estado Membro de proteger a saúde publica e, em particular, promover o acesso de medicamentos a todos, através da atribuição de licenças compulsivas, em casos de

emergencia nacional ou em outras circunstâncias de extrema urgência e em crises de saude publica, incluindo aquelas relacionadas com o HIV/SIDA, tuberculose, malaria ou outras epidemias que possam representar uma emergencia nacional.

Considerando ainda que

a tripla associaqiio dos farmacos lamivudina, stavudina e nevirapina provaram, nos últimos anos, um dos mais eficazes e económicos tratamentos com anti-retrovirais, mas os três diferentes detentores dos farmacos isolados nunca chegaram a um acordo para produzir a associação,

assim,

O Ministerio da Industria e Comércio da Republica de Mogambique, ao abrigo do disposto no Artigo 70, n°1 alínea b), do Decreto n°. 18/99 de 4 de Maio, decide atribuir uma licenga compulsiva n°.1/MIC/04 à empresa **Pharco Moqambique Lda.,** que apresentou um projecto para a produqiio local da mencionada tripla associaqiio, sob os nome de PHARCOVIR 30 e PHARCOVIR 40.

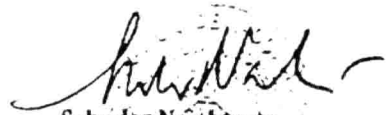
A comunicação desta decisão sera dada ao requerente e aos detentores da patente.

Tomando em consideração que o mencionado produto, de tripla associaqiio de farmacos, niio e comercializado em Moqambique pelos detentores da patente internacional e que e do interesse nacional manter o preqo final o mais baixo possivel, o valor total de royalties devidos aos detentores da patente niio excederá os 2% da receitas totais dos mencionados produtos, no final de cada ano fiscal da Pharco Moqambique Lda.

O Ministerio da Industria e Comércio, de acordo com o previsto no Artigo 70, ponto **6,** do Decreto n° 18/99 notificará as partes interessadas acerca da caducidade da presente licença compulsiva, assim que as condições de emergência nacional e extrema urgência, criadas pela pandemia do HIV/SIDA terminem.

O Governo da Republica de Moqambique reserva-se ao direito de rever esta licenga compulsiva, caso as condições nas quais ela é emitida se vierem a alterar.

Maputo, 5 de Abril de 2004



Salvador Namburete
Vice-Ministro

COMPULSORY LICENCE no. 01/MIC/04

The Government of Mozambique, conscious that the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under-development and misery and,

taking into consideration that.

high rates of morbidity and mortality have put Mozambique among the ten countries in Africa worst hit by this disease. Current estimates are that at the end of 2002 over 1,5 million Mozambicans were infected by HIV, of whom more than 100.000 are suffering from full-blown AIDS. The AIDS death toll is so far well over 200.000 and about 360.000 children have been orphaned by the pandemic,

and that,

In spite of multiplication and diversification of vigorous prevention campaigns the spread of the virus is still on a climbing trend as shown by the high number of infections,

considering further that,

Anti-retroviral drugs are already available, which prolong lives of those infected with HIV/AIDS, and that until now, at this day, the international patent owners have failed to make such drugs accessible at affordable prices to most of the Mozambican people,

and for such reason

on 14 November 2001 the World Trade Organization declared the right of each Member State to protect public health and in particular to promote access for medicines for all, by granting compulsory licenses in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics can represent a national emergency or other circumstances of extreme urgency.

Considering further that

a triple compound of lamivudine, stavudine and nevirapine has proved, in the last few years, to be one of the most effective and economical anti-retroviral treatment, but the three different international owners of such single drugs failed to reach an agreement to produce this combination,

therefore,

The Ministry of Commerce and Industry of the Republic of Mozambique, making use of the provision of article 70 no.1 point b), of Decree no. 18/99 of 4 May, has decided to grant the compulsory license no. 1/MIC/04 to the company **Pharco Moçambique Lda**, which has already presented a project for local manufacture of the mentioned triple compound under the names of PHARCOVIR 30 and PHARCOVIR 40.

Communication of this decision will be given to the applicant and to the patent owners.

In consideration that the mentioned product, a triple combination of drugs, is not marketed in Mozambique by the international patent owners and that it is in the national interest to keep the final price as lowest as possible, the total amount of royalties due to the patent owners shall not exceed 2% of the total turnover of the mentioned products, at the end of each financial year of Pharco Moçambique Lda.

This Ministry of Industry and Commerce, in accordance to provisions of Art. 70 point 6 of Decree no. 18/99 will notify the concerned parties of the expiration of the present compulsory license as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end.

The Government of the Republic of Mozambique reserves the right to review this compulsory license, in case the conditions in which it was issued are changed.

signed by

Salvador Namburete
Deputy Minister

Código da Propriedade Industrial

de Moçambique

Aprovado por Decreto n°. 18/99, de 4 de Mai

Industria2 Property Code

of Mozambique

Approved by Decree n°. 18/99 of May 4

Secção VII
Exploração da Patente

Subsecção I
Condições de Uso da Patente

ARTIGO 69
Obrigatoriedade de exploração

1. O titular da patente é obrigado directa ou indirectamente a explorar a sua invenção patenteada, comercializar os produtos obtidos de modo a abastecer as necessidades do mercado.

2. A exploração deve iniciar no prazo de três anos a contar da data de concessão da patente ou quatro anos apos o depósito do pedido.

3. A não exploração da invenqao nos prazos indicados nos numeros anteriores implica a concessão de licenqa obrigatória pelo titular da patente a terceiros.

ARTIGO 70
Licença obrigatoria

1. A invenqao poderá vir a ser explorada mediante autorização do Ministro de tutela, sem o consentimento do titular da patente, incluindo a utilização da invenqao pelo Governo ou por terceiros nos casos seguintes:

a) O potencial utilizador que tiver desenvolvido esforços no sentido de obter o consentimento do titular da patente em condições comerciais razoaveis e as negociações tiverem redundado em insucesso, num prazo

Section VII
Exploitation of the Patent

Subsection I
Conditions of Use of the Patent

ARTICLE 69
Obligation to exploit

1. The proprietor of a patent is under an obligation to, directly or indirectly, exploit his patented invention and market the products obtained in order to supply the needs of the market.

2. Exploitation shall commence within three years after the date on which the patent was awarded, or within four years after the application was filed.

3. Failure to exploit the invention within the prescribed periods shall result in the granting of a compulsory license by the proprietor to a third party.

ARTICLE 70
Compulsory license

1. The invention may be exploited under authorisation given by the responsible Ministry, without the consent of the proprietor of the patent, including use of the patent by the Government or by third parties, in the following instances:

a) When a potential user has endeavoured to obtain the consent of the proprietor of the patent under reasonable commercial conditions and negotiations have been unsuccessful for a reasonable time, and where the

razoavel e que manifeste a vontade de não ceder o uso da patente.

b) Utilização da patente em caso de situação de emergencia ou qualquer outra circunstância de extrema urgência podendo ser de caracter economico e social, ou para o desenvolvimento de outros sectores vitais da economia nacional se as circunstâncias o exigirem.

2. O pedido de licença obrigatoria dirigido ao órgão da administração da propriedade industrial deve ser acompanhado de prova de que o titular da patente recebeu por parte do requerente um pedido de licença contratual e que o requerente não obteve a licença em condições comerciais negociaveis e dentro de um prazo razoavel

3. O disposto no numero 2 nao se aplica aos casos de emergência nacional ou outras circunstancias de extrema urgência referentes a alínea b) do numero anterior

4. Em todos os casos mencionados no numero 1, o orgão da administração da propriedade industrial informara imediatamente ao titular da patente sobre os motivos da utilização da patente

5. O titular da patente recebera uma remuneração adequada, ajustada a cada caso concreto, tendo em conta o valor economico da autorização.

6. A extensão e a duração dessa

proprietor does not agree to transfer the use of the patent;

b) Use of the patent in a case of emergency or in any other circumstances of extreme urgency, either of an economic or a social nature, or for the development of other sectors that are vital to the national economy, when the circumstances so require.

2. The application for a compulsory license addressed to the industrial property administration office shall be accompanied by evidence that the proprietor of the patent received a request from the applicant for a contractual license and that the applicant failed to obtain the license under negotiated commercial conditions within a reasonable time.

3. The provisions of clause 2 shall not apply to cases of national emergency or other circumstances of extreme urgency referred to in paragraph b) of the preceding clause.

4. In all cases referred to in clause 1, the industrial property administration office shall immediately inform the proprietor of the patent about the grounds for using the patent.

5. The proprietor of the patent shall be given adequate remuneration, which shall be adjusted according to each particular case, taking into account the economic value of the authorisation.

6. The extent and duration of this use

utilização serão limitados aos fins para os quais a utilizaqao tiver sido autorizada.

7. A utilizaqao prevista nos termos do presente artigo não sera exclusiva, não podendo ser objecto de cessão de exploração. Tratando-se de uma empresa, a autorização sera concedida com a cedência da empresa ou seu objecto social no qual a invenção patenteada e explorada.

8. A exploração da invenção por terceiro ou por ente jurídico designado pelo Governo sera predominantemente destinada a abastecer o mercado em Moçambique.

shall be limited to the purposes for which it was authorised.

7. The use provided for under the terms of this article shall not be exclusive and shall not be the subject of an assignment of exploitation. In the case of an enterprise, the authorisation will be granted upon the transfer of the enterprise or corporate purpose under which the patented invention is exploited.

8. The exploitation of the invention by a third party or by a legal entity designated by the Government shall be aimed predominantly at supplying the market in Mozambique.

ARTIGO 71
Oposição a não exploração

O titular da patente pode a qualquer momento deduzir oposição ao pedido de licença obrigatoria de um terceiro, com o fundamento em factos que o excepcionem da imputabilidade da inobservância da lei.

ARTICLE 71
Objection against failure to exploit

The proprietor of the patent may at any time oppose an application by a third party for a compulsory license, on the basis of facts that show that the failure to observe the law was not attributable to him.

ARTIGO 72
Prova de exploração

1. A prova de exploração faz-se mediante um certificado oficial que deve ser emitido por organismo competente na area de exploração respectiva.

2. O certificado de exploração sera emitido no prazo de três meses a pedido do titular da patente ou seu representante, a contar da data do pedido, devendo ser expressamente indicado no certificado que a invenção esta sendo explorada.

ARTICLE 72
Proof of exploitation of a patent

1. Proof of exploitation shall be by means of an official certificate, which shall be issued by a competent entity in the area in question.

2. The exploitation certificate shall be issued at the request of the proprietor of the patent or his agent within three months from the date of the request and it shall indicate expressly that the invention is being exploited.

3. A condição de emissão do certificado é a existência de fabrico nas instalações industriais onde a invenção está a ser explorada e a verificação efectiva de comercialização do objecto da invenção.

3. The certificate shall be issued on the condition that manufacture is taking place at the industrial establishment that uses the invention and that there is effective marketing and sale of the object of the invention.

ZAMBIA

On September 21, the Zambian Minister of Domestic Trade and Consumer Affairs issued a compulsory license for lamivudine, stavudine and nevirapine. The license was granted to Pharco Ltd., a local producer, which will produce a triple fixed-dose combination. A maximum royalty rate of 2.5% applies.

Source: www.cptech.org

Telephone : 260 - 1- 226727
Telefax : 260 - 1- 226727
Telex : ZA 45630
Telegrams : COMIND
E-mail : cabmin@zamnet.zm
Website : www.mcti.gov.zm

REPUBLIC OF ZAMBIA

MINISTRY OF COMMERCE, TRADE AND INDUSTRY

OFFICE OF THE MINIS
P.O. BOX 31
LUSA

In reply please quote

No. .....

COMPULSORY LICENCE No. CL 01/2004

The Government of Zambia, conscious that the HIV / AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under development and misery;

and taking into consideration that high rates of morbidity and mortality have put Zambia among the ten countries in Africa most hit by this disease. Current estimates are that, at the end of 2003, over 917,718 Zambians were infected by HIV, of whom unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far in excess of 835,904 and about 760,504 children have been orphaned by this pandemic, creating a situation where 75% of house-holds in Zambia are caring for at least one orphan, and that children aged below 14 years headed more than 130,000 poverty stricken house holds out of a total of 1,805,000, and that;

Inspite of the multiplicity and diversity of vigorous prevention campaigns, the spread of the virus is still on an upward trend as shown by the high number of infections;

Taking into account the gravity of the situation being faced by most African

Considering further that;

A triple compound of Lamivudine, Stavudine and Nevirapine has proved, in the last few years to be one of the most effective and economical anti-retroviral treatment, but that the three different international owners of such single drugs failed to reach an agreement to produce this combination, and therefore;

The Ministry of Commerce, Trade and Industry of the Republic of Zambia, making use of the provisions of Section forty of the Patent Act, Chapter 400 of the Laws of Zambia, and Statutory Instrument No 83 of 2004 titled 'The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004' Regulation 3, has decided to grant a Compulsory Licence No. CL 01/2004 to PHARCO LTD, a company incorporated in Zambia, which has already presented a project proposal for the local manufacture of the mentioned triple compound under the names of Normavir 30 and Normavir 40.

It is further understood that the use or vending of the above mentioned drugs is subject to Regulation 4 of Statutory Instrument No 83 of 2004, titled 'The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorisation) Regulations, 2004' and therefore cannot be exported to any place outside Zambia.

Communication of this decision will be given to the applicant and to the patent right holders.

In consideration that the mentioned product a triple combination of drugs, is not marketed in Zambia by the International Patent owners and that it is in the national interest to keep the final price as low as possible, the total amount of royalties due to the patent right owners shall not exceed 2.5% of the total turnover of the mentioned products at the end of each financial year of PHARCO LTD.

The Ministry of Commerce, Trade and Industry shall ...

Text Version of the Compulsory License

Republic of Zambia
Ministry of Commerce, Trade, and Industry

COMPULSORY LICENSE No. CL 01/2004

The Government of Zambia, conscious that the HIV/AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under development and misery;

and taking into consideration that high rates of morbidity and mortality have put Zambia among the ten countries in Africa most hit by this disease. Current estimates are that, at the end of 2003, over **917,718** Zambians were infected by HIV, of whom an unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far in excess of **835,904** and about **750,504** children have been orphaned by this pandemic, creating a situation where 75% of households in Zambia are caring for at least one orphan, and that children aged below 14 years headed more than 130,000 poverty stricken households out of a total of 1,905,000, and that;

in spite of the multiplicity and diversity of vigorous prevention campaigns, the spread of the virus is still on an upward trend as shown by the high number of infections;

Taking into account the gravity of the situation being faced by most African Countries, including Zambia, the need to ensure access to drugs at affordable prices, while respecting the protection of intellectual property, is well recognized. For this reason; On 14 November, 2001 the World Trade Organization, while recognizing Members commitment to the TRIPS Agreement, declared the right of each Member State to take measures aimed at protecting public health and in particular to promote access to medicines for all, by utilising to the full, the flexibilities in the TRIPS Agreement relating to among others, the granting of compulsory licenses, in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crises including those relating to HIV/AIDS, tuberculosis, malaria, or other epidemics which can represent a national emergency or other circumstances of extreme urgency.

Considering further that;

A triple compound of Lamivudine, Stavudine and Nevirapine has proved, in the last few years, to be one of the most effective and economical anti-retroviral treatments, but that the three different international owners of such single drugs failed to reach an agreement to produce this combination, and therefore;

The Ministry of Commerce, Trade and Industry of the Republic of Zambia, making use of the provisions of Section forty of the Patent Act, Chapter 400 of the Laws of Zambia, and Statutory Instrument No 83 of 2004 titled "The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization) Regulations, 2004" Regulation 3, has decided to

grant a Compulsory License No. DC 01/2004 to PHARCO, LTD, a company incorporated in Zambia, which has already presented a project proposal for the local manufacture of the mentioned triple compound under the names of Normavir 30 and Normavir 40.

It is further understood that the use or vending of the above mentioned drugs is subject to Regulation 4 of Statutory Instrument No 83 of 2004, titled "The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization) Regulations, 2004" and therefore cannot be exported to any place outside Zambia.

Communication of this decision will be given to the applicant and to the patent right holders.

In consideration that the mentioned product, a triple combination of drugs, is not marketed in Zambia by the international Patent owners and that it is in the national interest to keep the final price as low as possible, the total amount of royalties due to the patent owner shall not exceed 2.5% of the total turnover of the mentioned products at the end of each financial year of PHARCO LTD.

The Ministry of Commerce, Trade and Industry, shall in accordance with Section forty one of the Patent Act notify the concerned parties of the expiration of the present Compulsory License as soon as conditions of national emergency and extreme urgency created by the HIV/AIDS pandemic will come to an end, or upon the expiry of the period of national emergency stipulated in Statutory Instrument No 38 of 2004 titled "The Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization) Regulations, 2004"

The Government of the Republic of Zambia reserves the right to review this Compulsory License should the conditions and circumstances under which it is granted should change.

Dipak K. Patel, MP
MINISTER

Ref: MCTI 104/1 Tc
Date: 21/09/2004

ERITREA

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ሚኒስትሪ ጥዕና

ة أرتريا
ة الصحة

The State of Eritrea
MINISTRY OF HEALTH

Ref. PM/833/2005

Date: 08 JUN 2005

To: IDA Procurement Services BV
P.O.Box 37348
1030 AH Amsterdam
The Netherlands
Fax: 0031-20-4031854

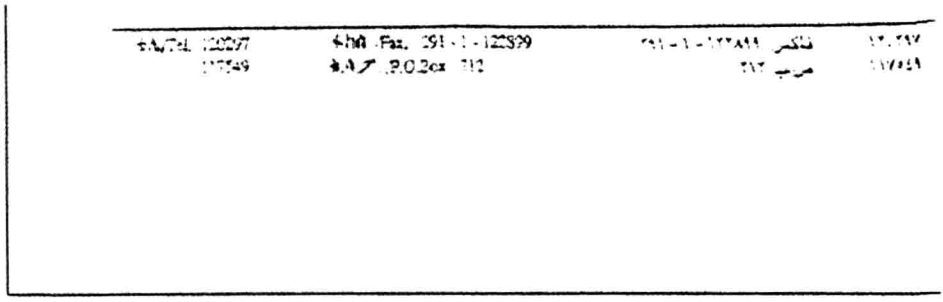
The Minister of Health Eritrea has carefully considered the WTO documentation, being the TRIPS Agreement and DOHA declaration regarding the patent situation of antiretroviral drugs and procurement thereof within the framework of the National HIV/AIDs program and hereby notifies you that:

Eritrea as an LDC and member of WTO declares an emergency situation with regards to HIV/AIDs. Therefore generic antiretroviral drugs may be imported into Eritrea following the a forementioned declarations. The a foresaid drugs will be used to treat people with HIV/AIDs without any commercial purpose. The Minister of Health hereby suggests that measures be taken to speed up supply of generic ARV's in order to continue a comprehensive treatment AIDs program in Eritrea.

Name: SALEH MEKY
MINISTER OF HEALTH

Signature:

Date: 08.06.05



SOUTH AFRICA

On September 19, 2002, the Treatment Action Campaign launched a complaint with South Africa's Competition Commission against GlaxoSmithKline and Boehringer Ingelheim. The complaint charged these corporations with excessive pricing in respect of ritonavir, lamivudine, ritonavir+lamivudine and nevirapine. GSK and BI were found to have contravened the Competition Act of 1998, and to have abused their dominant positions in their antiretroviral markets. The terms of the final settlement require the firms to:

1) extend the voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
2) grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
3) permit the licensees to export the ARVs to sub-Saharan African countries;
4) permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
5) permit licensees to combine the relevant ARV with other antiretroviral medicines; and
6) charge royalties of no more than 5% of the net sales of the relevant ARVs.

Source: www.cptech.org

SETTLEMENT AGREEMENT

entered into between, on the one hand,

the twelve COMPLAINANTS, named below,

in the complaint submitted by them ("the complaint")

to the Competition Commission in South Africa

in terms of the Competition Act,

under and in connection with case no 2002Sep226,

and, on the other hand,

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD,

GLAXO GROUP LIMITED and THE WELLCOME FOUNDATION

LIMITED (together defined as "GSK" below).

INTRODUCTION

1.1 The twelve complainants who are party to this agreement, and are referred to in this agreement as "**the complainants**", are the following:

1.1.1. **HAZEL TAU**

1.1.2. **NONTSIKELELO PATRICIA ZWEDALA**

1.1.3. **SINDISWA GODWANA**

1.1.4. **ISAAC MTHUTHUZELI SKOSANA**

1.1.5. **SR SUSAN ROBERTS**

1.1.6. **DR WILLIAM NKHANGWENI MMBARA**

1.1.7. **DR STEVEN MURRAY ANDREWS**

1.1.8. **DR WILLEM DANIEL FRANCOIS VENTER**

1.1.9. **THE CONGRESS OF SOUTH AFRICAN TRADE UNIONS**

1.1.10. **THE CHEMICAL, ENERGY, PAPER, PRINTING, WOOD AND ALLIED WORKERS' UNION**

1.1.11. **THE TREATMENT ACTION CAMPAIGN**

1.1.12. **THE AIDS CONSORTIUM.**

It is recorded that **MATOMELA PAUL NGUBANE**, who also submitted a complaint in connection with case no. 2002Sep226, passed away on 16 June 2003.

1.2. The complainants and GSK ("**the parties**") have agreed, and record herein, the terms of settlement upon which the complainants will withdraw against GSK their complaint currently before the Competition Commission.

1.3 Throughout this agreement, unless the context indicates otherwise —

1.3.1 "**GSK**" shall mean

(a) GLAXOSMITHKLINE SOUTH AFRICA (PTY) LTD (a company incorporated under the laws of South Africa having its registered office at Cansbrook Building, The Campus, 57 Sloane Street, Bryanston 2021, South Africa); and

(b) GLAXO GROUP LIMITED (a company incorporated under the laws of England having its registered office at Glaxo Wellcome House, Berkeley, Greenford, Middlesex UB6 0NN); and

(c) THE WELLCOME FOUNDATION LIMITED (a company incorporated under the laws of England having its registered office at Glaxo Wellcome House, Berkeley, Greenford, Middlesex UB6 0NN),

and the expression "GSK company" shall in addition include any affiliated company of any of the three companies named above;

1.3.2. "**affiliated company**" in relation to GSK shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with any company included in the definition of "GSK" (and, for the purposes of this definition, "control" shall mean the ability of any entity, whether through ownership of shares or otherwise, to procure that the affairs of another entity are conducted in accordance with its wishes);

1.3.3. "**relevant antiretrovirals**" shall mean the chemical compounds known as zidovudine and lamivudine, and shall, subject to 4.3, include all pharmaceutical compositions containing zidovudine and/or lamivudine for the prevention and/or treatment of HIV infection;

1.3.4. "**relevant patent(s)**" shall mean all South African patents and patent applications owned by any GSK company which claim any relevant antiretrovirals or any method of manufacture of them or any other aspect of them;

1.3.5. "**MCC**" shall mean the Medicines Control Council established under the South African Medicines and Related Substances Act No. 101 of 1965 as amended ("the Medicines Act"), or any successor thereto.

GSK's OBLIGATIONS

2.1. **The parties have agreed that GSK:**

2.1.1. will without delay extend the voluntary licence granted to Aspen Pharmacare Holdings Ltd ("**Aspen Pharmacare**"), in October 2001, in respect of the public sector to include the private sector;

2.1.2. will without delay further extend the voluntary licence granted to Aspen Pharmacare to permit Aspen Pharmacare, subject to any applicable law, to export to sub-Saharan African countries as listed in Annex 1 hereto, relevant antiretrovirals which have undergone any manufacturing or formulation process in South Africa in accordance with the said voluntary licence as extended in terms of 2.1.1;

2.1.3. will, within ten (10) days of the date on which this agreement is concluded, offer to grant a voluntary licence with respect to the relevant antiretrovirals to the joint-venture entity of Ranbaxy SA (Pty) Ltd and Adcock Ingram Holdings (Pty) Ltd, namely Thembalami Pharmaceuticals (Pty) Limited ("**Thembalami Pharmaceuticals**") on terms no less favourable than those granted to Aspen Pharmacare as contemplated in 2.1.1 and 2.1.2;

2.1.4. will entertain applications for the grant, on terms no less favourable than the most favourable terms granted to Aspen Pharmacare and/or Thembalami Pharmaceuticals, of two further voluntary licences to other entities, with respect to the relevant antiretrovirals, on the basis that, in

each case respectively — subject to 2.1.7 below where applicable — the applicant meets GSK's standard criteria relating to product quality and reliability, which criteria shall not be more onerous than the criteria which have been met by Aspen Pharmacare and/or Thembalami Pharmaceuticals, and which shall be reasonably applied;

2.1.5. will not unreasonably delay, refuse or withhold the grant of a voluntary licence to Thembalami Pharmaceuticals as contemplated in 2.1.3 or to an applicant as contemplated in 2.1.4, and, where the consent of any third party is required for the grant of any voluntary licence referred to in this agreement, GSK undertakes that it and its affiliated companies will use their best endeavours to obtain such consent;

2.1.6. undertakes that no GSK company will enforce any relevant patent or any equivalent patent of any GSK company in any of the countries listed in Annex 1 against conduct of a licensee complying with any licence or extension of a licence contemplated in this agreement;

2.1.7. will, to the extent that any licensee referred to or contemplated above does not agree, or is at any time unable for any reason beyond its control, to manufacture or formulate relevant antiretrovirals (whether in combination with any other antiretroviral medicines or otherwise) in South Africa, permit the importation of same by such licensee into South Africa, provided that all necessary MCC and other regulatory approvals are obtained, and provided further that no relevant antiretroviral so imported shall be re-exported from South Africa except in accordance with 2.1.2 above;

2.1.8. will not require the payment of royalties or similar charges in relation to any of the above licences in excess of five per cent (5%) of the net sales of the relevant antiretrovirals (and for this purpose "**net sales**" shall mean the total amount invoiced or otherwise due (after deduction of all taxes and discounts as shall be agreed between the

licensor and the licensee at the inception of the licence agreement) on sales by the licensee to third parties in terms of the relevant licence) — provided that, where a product sold contains zidovudine and/or lamivudine in combination with one or more other antiretroviral drug(s), the aforesaid maximum of 5% shall be reduced proportionally by means of the formula

$$\frac{(Z + L)}{(Z + L + X)} \times 5 = \text{applicable maximum \%}$$

where —

(a) Z = 1 where zidovudine is contained in the product and 0 where zidovudine is not contained in the product;

(b) L = 1 where lamivudine is contained in the product and 0 where lamivudine is not contained in the product;

(c) X = the number of other antiretroviral drugs contained in the product

(and, for the avoidance of doubt, it is recorded that the generic equivalent of Combivir® would attract a maximum royalty or similar charge of 5% of net sales),

2.1.9. will, in the event that any GSK company acquires or allows the acquisition or obtains the grant of any further patent in respect of relevant antiretrovirals which, if it had existed at the time of this agreement, would have been included within the meaning of "relevant patent(s)" as defined in 1.3.4 above or an equivalent patent as contemplated in 2.1.6 above, give effect *mutatis mutandis* to the provisions of 2.1.1 to 2.1.8 above in relation to such patent

2.2. **The parties record the following:**

2.2.1. Nothing in this agreement shall require any GSK company to grant licences under any patents existing outside South Africa and the countries listed in Annex 1.

2.2.2. In the event that licensee(s) combine zidovudine and/or lamivudine with any other pharmaceutical compounds, GSK may require such licensee(s) to suitably indemnify GSK against any third party claims including, without limitation, third party claims for patent infringement and product liability.

2.2.3. Nothing in this agreement shall be construed as an endorsement by any GSK company of the use of zidovudine and/or lamivudine in combination with any other pharmaceutical compounds where clinical, medical and regulatory approvals to GSK's standards for such combinations have not been obtained.

2.2.4. GSK intends, where appropriate and practicable, to endeavour to assist and support the South African government and non-governmental organisations supporting HIV prevention and treatment in South Africa, including in particular the antiretroviral treatment programme in the public sector.

2.2.5. It is the view of the complainants that all licensees and applicants for licences contemplated in this agreement should be strongly encouraged, so far as practicable, to manufacture and/or formulate relevant antiretrovirals in South Africa in the interests of developing local pharmaceutical manufacturing capacity and job creation. GSK will accordingly convey this view to all such licensees and applicants for licences. For the sake of clarity, it is recorded that GSK will not delay, refuse or withhold a licence as contemplated above on the basis that the applicant will not agree or will not be able as a licensee to

manufacture or formulate relevant antiretrovirals (whether in combination with other antiretroviral medicines or otherwise) in South Africa.

3. **COMPLAINANTS' OBLIGATIONS**

The parties have agreed that the complainants, in return for the obligations undertaken by GSK as set out above, will immediately withdraw the complaint, insofar as it relates to any GSK company, as contemplated by Rule 16(1) of the Rules for the Conduct of Proceedings in the Competition Commission, and immediately forward a copy of the notice of such withdrawal to GSK's legal representatives in South Africa. The complainants acknowledge that such withdrawal means that the complaint is terminated insofar as the complainants are concerned and that the complainants will thereby be precluded from referring the complaint to the Competition Tribunal.

4. **GENERAL**

4.1. Each signatory to this settlement agreement represents and warrants that he/she is duly authorised to act on behalf of the complainants or GSK, as the case may be, in entering into this settlement agreement.

4.2. This agreement shall be regarded as having been concluded upon the signature of the party whose representative signs last in time.

4.3. For the purposes of this agreement, a pharmaceutical composition containing zidovudine and/or lamivudine in combination with any other antiretroviral compound of which any GSK company owns the patent or patent application shall not be included in the definition of "**relevant antiretrovirals**"

4.4 Where, in order to give effect to this agreement at any time, it is necessary that any affiliated company do or refrain from doing anything, each of the companies named in the definition of "GSK" shall, without derogating from its own obligations as set out above, use its best endeavours to procure same

4.5. It is recorded that GSK's standard criteria relating to product quality and reliability referred to in 2.1.4 are set out in a document which has been identified to representatives of the complainants and which is to be held in trust as set out in 4.6.

4.6. It is recorded that attorneys SONNENBERG HOFFMANN GALOMBIK (or, failing them, attorneys designated by the chairperson of the Law Society of the Northern Provinces) will hold in trust for the parties,

4.6.1. a copy of the signed licence agreement referred to in 2.1.1;

4.6.2. a copy of each other signed licence agreement (and extension of a licence agreement) referred to in 2.1.2, 2.1.3 and 2.1.4;

4.6.3. a copy of the document containing GSK's standard criteria, referred to in 4.5,

on terms which have been agreed in writing between the parties prior to the conclusion of this agreement.

4.7. No party may cede any right or delegate any obligation provided for in this agreement without the written consent of the others.

4.8. This agreement shall be governed by and construed in accordance with South African law, and, insofar as may be necessary to render effective the jurisdiction of the High Court of South Africa, GSK hereby submits to such jurisdiction in relation to this agreement.

Thus done and signed at

on

Witness:

Full name:

Signature:

Signed on behalf of GSK by:

Full name:

Designation:

Signature:

Thus done and signed at

on

Witness:

Full name:

Signature:

Signed on behalf of the complainants by:

Full name:

Designation:

Signature:

ZIMBABWE

On May 24, 2002, Zimbabwe's Minister of Justice, Legal and Parliamentary Affairs declared a Period of Emergency in order to override antiretroviral drug patents.

1) General Notice 240 of 2002: Declaration of Period of Emergency.

2) Patents Act Article 35: Special Provisions as to State Use During Emergency.

The declaration announced an initial period of emergency of six months which was later extended to a further period of five years from January 2003 to December 2008 (in Statutory Instrument 32 of 2003)

In April 2003, a Zimbabwean registered company, Varichem Pharmaceuticals (Pvt.) Ltd. was granted authority to "make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the purpose of achieving the objectives of Statutory Instrument 32 of 2003".

3) Authority by the Minister of Justice, Legal and Parliamentary Affairs dated 8th April 2003

source: www.cptech.org

General Notice 240 of 2002

PATENTS ACT [CHAPTER 26:03]

Declaration of Period of Emergency (HIV/AIDS) Notice 2002

IT is hereby notified that the Minister of Justice, Legal and Parliamentary Affairs has, in terms of section 34 as read with section 35 of the Patents Act [Chapter 26:03] made the following notice:

1. This notice may be cited as the Declaration of Period of Emergency (HIV/AIDS) notice, 2002.

2. In view of the rapid spread of HIV/AIDS among the population of Zimbabwe, the Minister hereby declares an emergency for a period of six months, with effect from the date of promulgation of this notice, for the purpose of enabling the State or a person authorized by the Minister under section 34 of the Act

(a) to make or use any patented drug, including any antiretroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions;

(b) to import any generic drug used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions.

P. A. CHINAMASA

Minister of Justice, Legal and
Parliamentary Affairs.
24-5-002

Patents Act Article 35:

Special Provisions as to State Use During Emergency

Patents Act [Chapter 26:3] *Special provisions as to State use during emergency:*

35. (1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include the power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient -

a) for the efficient prosecution of any war in which Zimbabwe may be engaged; or
b) for the maintenance of supplies and services essential to the life of the community; or
c) for securing a sufficiency of supplies and services essential to the well-being of the community; or
d) for promoting the productivity of industry, commerce or agriculture; or
e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; or
f) generally, for ensuring that the whole resources of the community are available, for use, and are used, in a manner best calculated to serve the interests of the community; or
g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in brave distress as the result of war;

and any reference in that section or in section thirty-six to the service of the State shall be construed as including a reference to the purposes referred to in paragraphs (a) to (g).

(2) In subsection (1)-

"period of emergency" means any period beginning on such date as may be declared by the Minister, by statutory instrument, to be the commencement and ending on such date as may be so declared to be the termination of a period of emergency.

AUTHORITY BY THE MINISTER OF JUSTICE, LEGAL AND PARLIAMENTARY AFFAIRS

WHEREAS subsection (1) of section 34 of the Patents Act [*Chapter 26:03*] empowers the Minister to authorise any department of the State or any person to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State;

AND WHEREAS in terms of subsection (1) of section 35 of the Act, a period of Emergency on (HIV/AIDS) was declared by the Minister to run from 1st January 2003 to 31st December 2008 as provided for in Statutory Instrument 32 of 2003;

AND WHEREAS pursuant to that Declaration of a Period of Emergency **VARICHEM PHARMACEUTICALS (PRIVATE) LIMITED** has applied in terms of section 34 of the Act for authority to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State;

AND WHEREAS, it has appeared necessary and expedient for the sake of the requirements of section 35 of the Act to give such authority;

NOW THEREFORE, I, Patrick Anthony Chinamasa, (MP) and Minister of Justice, Legal and Parliamentary Affairs, (the Minister) with powers vested in me in terms of section 34 and 35 of the Act do hereby authorise-

VARICHEM PHARMACEUTICAL (PRIVATE) LIMITED to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the purpose of achieving the objectives of Statutory Instrument 32 of 2003.

MALAYSIA

On 29 October 2003 the Malaysian Minister of Domestic Trade and Consumer Affairs issued a two-year license to a local company to exploit patented inventions for didanosine (ddI), zidovudine (AZT) and lamivudine+zidovidine (Combivir). The license is issued under a provision on "government use" in the Malaysian patent law. The local company is authorized to import the drugs from a generic drug company in India. The drugs are for distribution to government hospitals. The company began to import the generic drugs at the beginning of 2004 and they are now being distributed in government hospitals at one seventh the previous cost of the patented drugs.

Source: www.cptech.org

COMPULSORY LICENSE

TRANSLATED FROM ORIGINAL

29 October 2003

Director of Operations

Syarikat Megah Pharma & Vaccines (M) Sdn Bhd
Suite E1103, Block E
Pusat Dagangan Phileo Damansara 1
46350 Petaling Jaya

Sir,

Authorisation for exploitation of patented invention in Malaysia

By virtue of Section 84(1)(a), Patents Act 1983, Syarikat Megah Pharma & Vaccines (M) Sdn Bhd (Company No: 552048-H) is hereby authorised to exploit patented inventions for the following drugs:

i. Didanosine 100mg tablets produced by Bristol-Myers Squibb;
ii. Didanosine 25mg tablet produced by Bristol-Myers Squibb;
iii. Zidovudine 100 mg capsule produced by GlaxoSmithKline; and
iv. Lamivudine 150mg + Zidovudine 300mg tablet produced by GlaxoSmithKline.

2. The authorisation is valid for two years, commencing November 1 2003.

It is subject to the following conditions:

i. the authorisation shall be limited to the importation of the above listed drugs from Cipla, India;

ii. the drugs to be imported shall only be for supply to government (public) hospitals

iii importation of the said drugs shall be subject to the terms and conditions as specified by the Ministry of Health, Malaysia;

iv. the quantity to be imported shall be as specified by the Ministry of Health, Malaysia;

v. all packaging of the drugs shall be labelled with the words "KEMENTERIAN KESIHATAN MALAYSIA" (Ministry of Health, Malaysia);

vi. the name (brand), shape or colouring of the tablets or capsules shall be differentiated from that of the patented products in Malaysia;

vii. the company shall be required to register the sale in the scheduled poisons register (please check this – think it refers to the Scheduled Poisons regulations);

viii. the ceiling price for the said drugs to be supplied to the Ministry of Health, Malaysia shall not exceed the following:

(a)	Didanosine 100 mg tablet	- RM74.58 (per box of 60 tablets)
(b)	Didanosine 25 mg tablet	- RM22.80 (per box of 60 tablets)
(c)	Zidovudine 100 mg capsules	- RM5.89 (one set of 10 capsules)
(d)	Lamivudine 150mg + Zidovudine 300mg tablet	- RM153.50 (per box of 60 tablets)

ix. Payment of compensation shall be made to the patent holder(s) within 2 months of each import of the said drugs. The rate of compensation is to be determined at a later date.

3. The above terms and conditions may be amended or varied as deemed appropriate.

4. The authorisation may be terminated at any time in the event of non-compliance with the terms and conditions as specified above.

(signature)
(TAN SRI DATO'MUHYIDDIN BIN HJ. MOHD YASSIN)
(Minister of Domestic Trade and Consumer Affairs,
Malaysia)

SAMPLE FORM APPLICATION FOR COMPULSORY LICENS MALAYSIA

II. LICENSOR:

Name : .....

Address : .....

.....

III. LICENSEE:

Name : .....

Address : .....

.....

IV. REQUEST:

The parties to the licence contract identified above request the Registrar to record in the Register the

expiry ☐ or termination ☐

of the licence contract

V. ADDITIONAL INFORMATION

The following items accompany this Form:

(a) documentation evidencing the above fact (specify)

(b) other (specify)

VI. SIGNATURE: .....

***(Licensor/Agent for Licensor)* *(Date)*

If Agent, indicate Agent's Registration No: .....

.....

***(Licensee/Agent for Licensee)* *(Date)*

If Agent, indicate Agent's Registration No: .....

Patents Form No. 11
PATENTS ACT 1983

APPLICATION FOR COMPULSORY LICENCE
(Regulations 38)

To: The Registrar of Patents
Patent Registration Office
Kuala Lumpur
Malaysia

For Official Use

APPLICATION No.: .....

Filing Date: .....

Application received on: .....

Fee received on: .....

Amount: .....

* Cheque/Postal Order/Money Order/Draft/Cash

No. .....

Date of mailing: .....

Please submit one copy of this Form together with the prescribed fee.

Applicant's or Agent's file reference

.....

I. IN THE MATTER OF:

Patent Application No. ..... Filing Date: .....

* Delete whichever does not apply.

** Type name under signature and delete whichever does not apply.

II. APPLICANT:

Name : .....

Address : .....

.....

Address for service in Malaysia:.....

.....

Nationality:.....

* Permanent residence or principal place of business:

.....

.....

Telephone Number (if any)	Fax Number (if any)
.....	.....

III. REQUEST

The above applicant applies to the Registrar to transmit to the Board the request, in respect of the patent identified above, for the grant of a compulsory licence under section 49 and/or 49A of the Patents Act 1983, in accordance with the terms proposed in Part IV of this Form and upon the grounds set out in Part V of this Form.

IV. PROPOSED TERMS:

A statement setting out the amount of royalty, the conditions of the exploitation of the patent and the restriction of the rights of the licensor or licensee, as the case may be, is attached.

V. ** STATEMENT OF GROUNDS attached.

VI. ADDITIONAL INFORMATION

The following items accompany this Form:

(a) evidence that the patent owner has received a request from the applicant to obtain a licence contract but that he has been unable to obtain such a licence on reasonable terms and within a reasonable time ☐

(b) plan according to which the applicant intends to work the patented invention, including evidence that he has the ability to do so in Malaysia ☐

(c) other (specify) ☐

.....

VII. SIGNATURE..... .....

***(Applicant/Agent) (Date)

If Agent, indicate Agent's Registration No.: .....

* Delete whichever does not apply

** The ground upon which the request is based shall be indicated by a reference to the statutory provision the applicant considers applicable (section 49(1)(a) and/or 49(1)(b) and/or 49A of the Patents Act 1983) and to the facts he considers as justifying the grant of a compulsory licence.

*** Type name under signature and delete whichever does not apply.

INDONESIA

On October 5, 2004, Indonesia issued a compulsory license for lamivudine and nevirapine. The license is for government use, and includes a royalty rate of 0.5% of the net selling value. The license is for a local company to manufacture the drugs.

Source: www.cptech.org

DECREE OF THE PRESIDENT REPUBLIC OF INDONESIA
NUMBER 83 YEAR 2004
REGARDING
EXPLOITATION OF PATENT BY THE GOVERNMENT ON
ANTI RETROVIRAL DRUGS

THE PRESIDENT OF THE REPUBLIC OF INDONESIA

Considering:
a. that in line with the urgent need in the effort to control HIV/AIDS epidemic in Indonesia, it is necessary to provide access to Anti Retroviral Drugs that are still protected under Patent;
b. that as exploitation of Article 5 of Government Regulation No 27 of 2004 regarding the Mechanism of Patent Exploitation by the Government, it is necessary to stipulate a Presidential Decree regarding Patent Exploitation of Anti Retroviral Drugs by the Government;

In view of:
1. Article 4 paragraph (1) of the Constitution of 1945 as amended by the Fourth Amendment of the Constitution of 1945;
2. Law No. 23 of 1992 regarding Health (State Gazette of 1992 No. 100, Supplementary State Gazette No. 3495);
3. Law No. 14 of 2001 regarding Patent (State Gazette of 2001 No. 109, Supplementary State Gazette No. 4130);
4. Government Regulation No. 27 of 2004 regarding Patent Exploitation Mechanism by the Government (State Gazette of 2004 No. 106, Supplementary State Gazette No. 4423);

DECIDES:

Stipulating: DECREE OF THE PRESIDENT REGARDING PATENT EXPLOITATION OF ANTI RETROVIRAL DRUGS BY THE GOVERNMENT.

First: The exploitation of patent of Antiretroviral Drugs by the Government is meant to comply the urgent need of community in the effort to control HIV/AIDS epidemic.

Secondly: The type, name of Patent Holder, Patent number and period of

Patent exploitation of the Antiretroviral Drugs as referred to the First Dictum is attached in the Annex of this Decree.

Thirdly Minister of Health may appoint a Pharmaceutical Factory as the Patent exploiter for and on behalf of the Government to exploit the Patent by taking into account the recommendations from Head of National Drug and Food Control Authority.

Fourth: The Government shall give a 0.5% compensation fee of the net selling value of Anti Retroviral Drugs to the Patent Holder.

Fifth: This Decree shall take effect on the date of its enactment.

Enacted in Jakarta
On 5 October 2004
THE PRESIDENT OF REPUBLIC OF INDONESIA
signed
MEGAWATI SOEKARNOPUTRI

For true copy
Deputy Cabinet Secretary
Legal and Legislation Department,

Lambock V Nahattands

ANNEX
PRESIDENTIAL DECREE OF REPUBLIC OF INDONESIA
NUMBER : 83 YEAR 2004
DATED : 5 OCTOBER 2004

TYPE, NAME OF PATENT HOLDER, PATENT NUMBER, AND PERIOD OF PATENT EXPLOITATION OF ANTI RETROVIRAL DRUGS

NO	TYPE	NAME OF PATENT HOLDER	PATENT NUMBER	PERIOD OF PATENT EXPLOITATION
1	Nevirapine	Boehringer Ingelheim (BI)	ID 0001338	7 years
2	Lamivudine	Biochem Pharma INC	ID 0002473	8 years

THE PRESIDENT OF REPUBLIC OF INDONESIA
Signed
MEGAWATI SOEKARNOPUTRI

For true copy
Deputy Cabinet Secretary
Legal and Legislation Department,

Lambock V Nahattands

DECREE OF THE PRESIDENT REPUBLIC OF INDONESIA

NUMBER 76 OF 2012

REGARDING

EXPLOITATION OF PATENT BY THE GOVERNMENT ON

ANTIVIRALS AND ANTIRETROVIRALS MEDICINES

BY THE GRACE OF GOD MAHASA ESA

THE PRESIDENT OF THE REPUBLIC OF INDONESIA,

Considering: a. that in line with the urgent need in the effort to control Human Immunodeficiency Virus-Acquired Immuno Deficiency Syndrome (HIV / AIDS) and Hepatitis B in Indonesia, it is necessary to continue and expand the access policies to provide access to Antiviral and Antiretroviral medicines that are still protected by patent;

b. that Presidential Decree No. 83 Year 2004 Implementation of Patents Against Government Antiretroviral medications as amended by Presidential Decree No. 6 of 2007 on the amendment of Presidential Decree No. 83 Implementation of Patents in 2004 by the Government Against Anti-Retroviral Medicines are already no longer sufficient as legal basis for implementing policies as referred in paragraph a;

c. that by consideration as referred to in paragraphs a and b, it establishes Presidential Decree on the Exploitation of Patent by the Government on Antiviral and Antiretroviral Medicines;

Given: ...

In view of : 1. Article 4 paragraph (1) of the Constitution of the Republic Indonesia 1945;

2. Law No. 14 of 2001 on Patents (State Gazette of the Republic of Indonesia Year 2001 Number 109, Supplement to Statute Indonesia Number 4130);

3. Law Number 36th of 2009 regarding Health (State Gazette of the Republic of Indonesia Year 2009 No. 144, Supplement to Statute Indonesia Number 5063);

4. Government Regulation No. 27 of 2004 regarding Patent Exploitation Mechanism by the Government (State The Republic of Indonesia Year 2004 Number 106, Additional State Gazette No. 4423);

DECIDES:

Stipulating: PRESIDENTAL DECREE REGARDING PATENT EXPLOITATION OF THE ANTIVIRAL AND ANTIRETROVIRAL DRUGS.

Article 1

The Exploitation of Antiviral and Antiretroviral medicines by the Government is intended to meet availability and urgent needs of community for Antiviral and Antiretroviral for treatment of Human Immunodeficiency Virus-Acquired Immuno Deficiency Syndrome (HIV / AIDS) and Hepatitis B.

Article 2

Active substance name, the name of the patent holder, patent number and period of Patent exploitation of the Antiviral and Antiretroviral medicines as referred to in Article 1, are listed in the Annex hereto.

Article 3

The ministry of Health appoints Pharmaceutical industry as the patent exploiter for and on behalf of the Government to exploit the Patent for Antiviral and Antiretroviral medicines as referred to in Article 1

Article 4

Pharmaceutical Industry shall give a 0.5% (zero point five percent) compensation fee of the net selling value of Antiviral and Antiretroviral drug medicines to the Patent Holder.

Article 5

(1) Granting rights as referred to in Article 4, held every year in accordance net selling drugs Antiviral and Antiretroviral.

(2) The ...

(2) The remuneration referred to in paragraph (1) ceases when the patent is expired period protection or end result presence cancellation in accordance with applicable laws and invitation.

Article 6

At the time of the enactment of this Presidential Decree Presidential Decree No. 83 of 2004 regarding exploitation of patent by the Government On Anti-Retroviral Drugs as amended by Presidential Decree Number 6 of 2007 on the amendment of Decision Presidential Decree No. 83 Year 2004 regarding exploitation of patent by the Government On Anti-Retroviral Drugs, revoked and declared invalid.

Article 7

Presidential Decree is effective on the date of its enactment.

So that everyone knows, it is ordered Presidential Decree is promulgated in the Gazette of the Republic of Indonesia.

Enacted in Jakarta

On 3 September 2012

PRESIDENT OF REPUBLIC OF INDONESIA,

DR. H. SUSILO BAMBANG YUDHOYONO

Enacted in Jakarta

On the

MINISTER OF JUSTICE AND HUMAN RIGHTS

REPUBLIC OF INDONESIA,

AMIR SYAMSUDIN

REPUBLIC OF INDONESIA NUMBER YEAR 2012

APPENDIX

PRESIDENTAL DECREE OF REPUBLIC OF INDONESIA

NUMBER 76 OF 2012

REGARDING

EXPLOITATION OF PATENTS BY THE GOVERNMENT ON ANTIVIRAL AND ANTIRETROVIRALS MEDICINES

ACTIVE SUBSTANCE NAME, NAME OF PATENT HOLDER, PATENT NUMBER, AND DURATION OF PATENTS FOR ANTIVIRAL AND ANTIRETROVIRAL MEDICINES

NO.	NAME OF ACTIVE SUBSTANCES	NAME OF PATENT HOLDERS	PATENT NUMBER	DURATION OF PATENT
1.	Efavirenz	Merck & Co., INC	ID 0005812	Until the end of patent period, August 7, 2013
2.	Abacavir	Glaxo Group Limited	ID 0011367	Until the end of patent period, May 14, 2018
3.	Didanosin	Bristol - Myers Squibb Company	ID 0010163	Until the end of patent period, August 6, 2018
4.	Combination Lopinavir and Ritonavir	Abbott Laboratories	ID 0023461	Until the end of patent period, August 23, 2018
5.	Tenofovir	Gilead Sciences, Inc.	ID 0007658	Until the end of patent period, July 23, 2018
6.	Combination Tenofovir and Emtrisitabin Combination Tenofovir, Emtrisitabin and Evafirenz	Gilead Sciences, Inc.	ID P0029476	Until the end of patent period, 3 November 2024

PRESIDENT OF THE REPUBLIC OF INDONESIA,

DR. H. SUSILO BAMBANG YUDHOYONO

THAILAND

DECREE OF DEPARTMENT OF DISEASE CONTROL, MINISTRY OF PUBLIC HEALTH, REGARDING

EXPLOITATION OF PATENT ON DRUGS & MEDICAL SUPPLIES BY THE GOVERNMENT

ON COMBINATION DRUG BETWEEN LOPINAVIR & RITONAVIR

Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542)states that, for the public use, ministry or department may exploit any patent without further negotiation with the patent holder. This implication makes clear that, for non-commercial use, especially in public affairs of the government such as public health services, government is well within its rights.

The situation of HIV spreading is the key problem of Thai public health. More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy because of patent protection by law, then there's no competition. The government cannot allocate enough budget. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2007 (B.E. 2550) is only 3,855.6 million baht for the target group of 108,000 patients. Some of this group have resistance to the first line ARVs and have to move to the second line.

Lopinavir + Ritonavir under the tradename Kaletra is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of second line Anti-retrovirals. Because it's protected by patent, no one can produce or import to share the market. So, it's price is much higher than generic products in some other country. With this higher price, the budget allocated from the Thai Government can only cover some patients with it, whereas the rest has to face with fatal opportunistic infections. If this ARVs formula could be produced or imported, the lower price would help more accessible.

Under the Doha Declaration on TRIPs and Public Health , it notifies that each member state has the right to protect public health in particular to promote access for medicines for all, by granting compulsory licenses in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics. While Section 51 of Thailand's Patent Act defines the right of "any ministry, or department of the Government," "by themselves or through others," to exercise the rights in any patent "for public consumption" , without commercial use as mentioned above.

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Kaletra (or Lopinavir+Ritonavir as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:-

(1) The use of the above patent rights are effective from today to the 31st January 2012.

(2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 50,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social

employees medical benefits scheme..

(3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Lopinavir+Ritonavir will be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.

This decree is announced to the public.

Issue on 29 th January 2007.

(Mr.Thawach Suntrajarn)
Director General of The Department of Disease Control

Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public use of patent for Pharmaceutical Products

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542), ministries, bureaus and departments are allowed to use the patent rights of a product for public interests without prior permission from the patent owners. The public use of patent rights clearly aimed for non-commercial purposes and for public interests. In other word, the government has a right to use any patent right for public health services.

It is generally known that HIV/AIDS is an important public health problem. More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2006 (B.E. 2549) is only 2,796.2 million baht for the target group of 82,000 patients.

There are several effective anti-retrovirals that can extend the life of HIV infected individuals currentl available in the Thai market. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their accessibility under the universal access policy.

Efavirenz is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of Anti-retrovirals. However, the price of the patented Efavirenz is twice of those generics produced by WHO certified GMP factories in India. With this higher price, the budget allocated from the Thai Government can only cover some patients with Efavirenz, whereas the rest has to use other non patented more toxic anti-retrovirals

According to the Doha Declaration on the TRIPS Agreement and Public Health, member countries hav a right to issue a safeguard measure to protect public health, especially for universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products. Based on the Declaration, the compulsory licensing measure can be used for the purposes of emergency cases and public uses. These flexibilities applied to drugs used for treatment of HIV/AIDS, tuberculosis, malaria, and other outbreaks. Under the Thai Patent Act, ministries, bureau, and departments are allowed to use the patent rights of any products for non-commercial public uses.

By the virtue of provisions of Article 51 of the Thai Patent Act B.E. 2522 (as amended by the Thai Paten Act no.2 B.E. 2535 and no.3 B.E. 2542), the Department of Disease Control, Ministry of Public Health, thus use the patent right of a medicine called Stocrin® (or efavirenz as a generic name) and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Article 36 of the Thai Patent Act B.E. 2522 (as amended by the Thai Patent Act no.2 B.E. 2535 and no.3 B.E. 2542) under these conditions:-

(1) The use of the above patent rights are effective from today to the 31st December 2011.
(2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 200,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employees medical benefits scheme..
(3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value of the imported or locally produced Efavirenz will be paid to the patent holder.

The Department of Disease Control, Ministry of Public Health will notify the patent owner and the Department of Intellectual Property, Ministry of

Commerce immediately.

Announced on 29th November 2006

Singed Thawatch Soontarajarn
(Mr. Thawacht Soontatajarn)
Director General
Department of Disease Control

Garuda

Translation

Ministry of Public Health Announcement
Regarding Exploitation of Patents on Drugs and Medical Supplies for Clopidogrel

As part of Section 51 of the Thai Patent Act B.E. 2522 as amended by the Thai Patent Act no.2 B.E.2535 and no.3 B.E. 2542 affirms that in order to carry out any service for public consumption, ministry or bureau or department of the government may exercise the rights in any patent without the requirement of prior negotiation with the patentee. Its objective is clearly aimed for non-commercial purposes and public interests, for example, public health service.

Myocardial ischemia and cerebro-vascular accident are the most serious public health burden because of high mortality and disability loss. Its mortality rate is in top three annual ranking. Both diseases cause much DALY loss and are in top ten ranking for Thai male and female. Even though these diseases could be prevented by diet control, mental and physical exercise, but the incidents are high and need medicine for treatment and secondary prevention from thrombosis which leads to morbidity and mortality.

Clopidogrel or the trade name in Thailand namely Plavix® has evidence based effectiveness for prevention of myocardial ischemia, cerebro-vascular accident and coronary stent implantation by inhibition of platelet aggregation. However, the medicine is expensive thus has hindered their accessibility. Owing to its patent exclusive right, there is no competition. Government Pharmaceutical Organization or other manufacturers can not produce or import the medicine for price competition.

Regarding the diseases incidents, only 45 millions members of the Universal Coverage scheme will need for 20.5 million pills per annum. However, since the high price and limited budget, 20 percent of patients covered under Universal Coverage scheme can access to the medicine. As a result of provision of market competition by imported or locally produced generics, price will reduce dramatically and accessibility will increase 6 to 12 times which will conform to the Universal Coverage policy.

Under the Doha Declaration on TRIPS and Public Health stated that WTO members have rights to protect public health and, in particular, to promote access to medicines for all by granting compulsory licenses in a national emergency and public needs. In addition, the Thai Patent Act states that the ministry or bureau or department of the Government may exercise the rights in any patent for public non-commercial consumption.

By the virtue of provisions of Section 51 of the Thai Patent Act B.E. 2522 as amended by the Thai Patent Act no.2 B.E.2535 and no.3 B.E. 2542, Ministry of Public Health, thus use the patent right of medicine called Plavix® and medicines contain Clopidogrel in all formulas, including its derivatives patented in Thailand and endorse the Government Pharmaceutical Organization of Thailand to exercise the rights contain within Para 1 of Section 36 of the Thai Patent Act B.E.2522 as amended by the Thai Patent Act no.2 B.E.2535 and no.3 B.E.2542 under these conditions:-

(1) The use of the above Patent rights is effective from today until the patent expired or no essential need.
(2) The use of the provision of generic drugs of Clopidogrel is unlimited for patients covered under the National Health Security Act B.E.2545, Social Security Act B.E.2533 and Civil Servants and Government Employees Medical Benefit Scheme but is under doctors' judgment
(3) A royalty fee of 0.5 percent of the Government Pharmaceutical Organization's total sale value

Ministry of Public Health will notify the patentee and the Department of Intellectual Property in writing without delay.

This announces to the public.

Issue date 25 January B.E.2550

(Mr Prat Boonyawongvirot)
Permanent Secretary, Ministry of Public Health

BRAZIL

STD·AIDS

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04/05/07 (dd/mm/yy)

Brazil issues compulsory license for Efavirenz

For the first time, Brazil will issue a compulsory license for a drug. The president of the Republic, Luiz Inácio Lula da Silva, signed on this Friday (04), in Brasília (DF), a decree to sanction the compulsory licensing of the antiretroviral drug Efavirenz. The company that holds the patent for the product, Merck, had been given seven days in which to make new proposal after the Minister of Health, José Gomes Temporão, declared the drug to be of public interest by signing Ministerial Ordinance No. 886 on April 24th. During this period the laboratory offered a discount of 30% on the current price of US$ 1.59 per tablet paid by the Federal Government. This proposal was considered to be unsatisfactory, since Brazil would be able to obtain the product elsewhere for US$ 0.45.

Compulsory licensing enables the Ministry of Health to import generic versions of Efavirenz from laboratories that are prequalified by the World Health Organization (WHO). The quality, safety and effectiveness of the imported drug offered to Brazilian patients are guaranteed by the bioequivalence and bioavailability tests required to be performed. Currently, three Indian laboratories meet the WHO requirements, namely Cipla, Ranbaxy and Aurobindo.

The antiretroviral drug Efavirenz is the most used imported drug in AIDS treatment. Currently, 38% of AIDS patients take Efavirenz as part of their treatment scheme. It is estimated that by the end of this year, 75,000 of Brazil's 200,000 AIDS patients will be taking the drug.

At the current prices charged by Merck in Brazil, the annual cost per patient is equivalent to US$ 580, representing budgeted expenditure of US$ 42.9 million for the year 2007. The prices charged for the generic product result in an annual cost per patient that varies between US$ 163.22 and US$ 166.36. Based on these amounts, under compulsory licensing, expenditure reduction in 2007 will be around US$ 30 million. Savings of US$ 236.8 million are estimated to be made by the year 2012, when the Efavirenz patent expires.

The decision of the Brazilian government is in absolute compliance with international requirements and with Brazilian legislation. Compulsory licensing in the public interest is taken to be a legitimate and necessary measure to ensure that all patients who are provided with Efavirenz via the Ministry of Health's National STD and AIDS Programme have access

to it.

Public interest – Compulsory licensing is a flexibility provided for by article 31 of the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). This practice is used by developed countries, such as Italy and Canada in relation to pharmaceutical products and also by developing countries. In the case of antiretroviral drugs, Mozambique, Malaysia, Indonesia and Thailand have already made use of this provision. Furthermore, Thailand recently issued compulsory licensing for Efavirenz.

In Brazil, compulsory licensing can be implemented in the event of circumstances provided for in the Brazilian Industrial Property Law, such as the abusive exercising of patent rights, the abuse of economic power, absence of local production, unsatisfactory commercialization, national emergency and public interest.

In the case of the antiretroviral drug Efavirenz, compulsory licensing has been granted based on the public interest in the light of the need to ensure the viability of the National DST/AIDS Programme. Compulsory licensing in the public interest must be granted for non-commercial use, non-exclusive production, and temporarily for a fixed period of time, although it may be extended and remain in force for as long as the public interest exists. It must be emphasized that independently of this the remuneration due to the patent holder remains ensured.

See the Decree N° 6.108, of May 4th 2007, that grants compulsory licence of Efavirenz.
PDF (13 KB)

See also the Ministerial Ordinance N° 886, of April 24th 2007, that declares Efavirenz to be of public interest.
PDF (1,5 KB)

Further information
Ministry of Health Press Office
National STD/AIDS Programme
Tel.: +55 61 3448-8100 / 3448-8088
E-mail: ascomsa@aids.gov.br
Portal: www.aids.gov.br

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India

BEFORE THE CONTROLLER OF PATENTS
MUMBAI

Present: Mr. P. H. Kurian

Compulsory License Application No. 1 of 2011

IN THE MATTER OF:

NATCO PHARMA LIMITED: .....APPLICANT

Represented by: Ms. Rajeshwari H., Advocate & Patent Agent

AND

BAYER CORPORATION ..... PATENTEE/OPPONENT

Represented by: Sh. Sudhir Chandra Aggarwal, Senior Advocate.
Sh. Sanjay Kumar, Advocate & Patent Agent
Ms. Arpita Sawhney, Advocate
Sh. Rahul Kumar, Advocate

APPLICATION FOR COMPULSORY LICENCE UNDER SECTION 84(1) OF THE PATENTS ACT, 1970 IN RESPECT OF PATENT NO.215758.

1. **Overview**

The patent system is a carefully crafted bargain that rewards an inventor in lieu of his contribution towards the society. The inventor is granted an exclusive right for a limited period: a) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using,

offering for sale, selling or importing for those purposes that product; and b) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process. The benefit derived by the society, *inter alia*, in granting such a comprehensive right to the inventor for twenty years, is the enrichment of knowledge in public domain, which can be utilized to invent further. This cycle goes on and on to take the nation towards socio-economic prosperity. Without the presence of a Patent system, the inventor will not be encouraged to disclose his invention to public and may prefer to keep it as a trade secret, which may result in innovative sluggishness, thereby adversely affecting the prosperity of a nation.

From its very nature, a right cannot be absolute. Whenever conferred upon a patentee, the right also carries accompanying obligations towards the public at large. These rights and obligations, if religiously enjoyed and discharged, will balance out each other. A slight imbalance may fetch highly undesirable results. It is this fine balance of rights and obligations that is in question in this case.

2. **History of compulsory licenses**

When TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement was introduced in 1994, it reduced the discretionary powers of WTO Members to customize key elements of their national intellectual property regimes. In January 1995, when WTO came into existence, the TRIPS Agreement, building on the existing multilateral treaties administered by the World Intellectual Property Organization (WIPO), introduced minimum standards for

protecting and enforcing intellectual property rights to an extent previously unseen at the global level, including new monitoring and dispute settlement mechanisms. Article 27.1 of the TRIPS Agreement requires WTO Members to make patents "available for any inventions, whether products or processes, in all fields of technology", which includes patents for pharmaceutical processes and products. At the same time, TRIPS also provides a reasonable fetter on the rights of the Patentee in the form of Article 30 and 31, in line with Paris Convention, thereby allowing member countries to enact provisions, *inter alia*, for granting compulsory license to prevent the abuse of patent right.

Compulsory License (CL) under the Patents system is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the State. The WTO states compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. It has been in existence since the 1830s. CL has been reported to be popular in Britain as early as 1850s. Later, this system was recognized by the international community through the Paris Convention of 1883. It is also one of the flexibilities on patent protection included in the TRIPS Agreement.

Provisions for granting a compulsory license exists in the Patent Laws of various countries such as Canada, France, UK, USA, Australia (developed countries), and Zimbabwe, Ghana, Brazil, Equador, Malaysia, Thailand and India (developing countries). In fact, compulsory licenses are being issued by developed as well as developing countries even in recent times.

India joined TRIPS and the deadline for complying with TRIPS obligations was January 1, 2005. The Patents Act, 1970 was amended

thrice to make it fully TRIPS compliant i.e. in 1999, 2002 and finally in 2005. The Patents Act, 1970, as enacted originally, contained a provision for grant of a compulsory license, in case the aforementioned balance is disturbed. However, vide the Patents (Amendment) Act, 2002, the provisions relating to compulsory license, i.e. Chapter XVI of the Patents Act, 1970 was substituted with a completely new one. The Patents (Amendment) Act, 2005 allowed product patents to be granted for drugs, which was not allowed under the 1970 Act.

Present case is the first of its kind in the history of Patents Act, 1970, wherein the provisions of Section 84 have been invoked by the Applicant herein for seeking the grant of a compulsory license. As such, there is no precedent to guide this tribunal. Relevant persuasive material has been submitted by both parties. In order to appreciate all the issue involved in the present litigation, the hearings went on for three days for a total of eighteen hours. Reasonable research has also been conducted by this tribunal to study, *inter alia*, the provisions of the International Agreements and Conventions on Intellectual Property Rights as well as laws of other TRIPS member countries to arrive at this order. This includes the articles published by WHO, UNDP, Mr.Carlos M. Correa, University of Buenos Aires, & Professor Shamnad Basheer, The West Bengal National University of Juridical Sciences, Kolkata.

3. **The Patentee**

M/s. Bayer Corporation, 100 Bayer Road, Pittsburg, PA 15205-9741, USA (hereinafter referred to as 'patentee'), an internationally renowned manufacturer of innovative drugs, invented a drug called 'Sorafenib' (Carboxy Substituted Diphenyl Ureas) useful in the treatment of advanced stage liver and kidney cancer in the 1990s. The patentee first applied for a patent in the United States Patent and Trade

Mark Office on 13.01.1999 and subsequently filed a PCT International Application on PCT/US00/000648 in the 12.01.2000. The Patentee entered the national phase in India on 05.07.2001. After examination under the provisions of the Patents Act, 1970, a patent was granted on 03.03.2008. The Patentee has also obtained patents in many other countries for the same drug including members of the European Patent Office.

In the meanwhile, the Patentee developed the drug and launched it in 2005 under the trade name Nexavar (hereinafter referred to as the 'drug') for treatment of Renal Cell Carcinoma-RCC (kidney cancer) and subsequently got additional approval for treatment of Hepatocellular Carcinoma-HCC (liver cancer) in 2007. The Patentee received the regulatory approval for importing and marketing the drug in India and launched it in India in the year 2008.

4. **The Applicant**

The Applicant herein M/s. Natco Pharma Ltd, Natco House, Road No. 2, Banjara Hills, Hyderabad-500033, Andhra Pradesh, India (hereinafter referred to as 'Applicant') is a reputed Indian generic drug manufacturer. The Applicant has developed the process to manufacture this drug and received a license from the Drug Controller General of India for manufacturing the drug in bulk and for marketing it in the form of tablets in April 2011.

5. **The drug**

'Sorafenib tosylate', which is a compound covered by Patent No.215758 and sold under the brand name NEXAVAR by the Patentee is used for the treatment at the advanced stages of kidney and liver cancer. The drug stops the growth of new blood vessels and targets

other important cellular growth factors. It is pertinent to mention that the drug is not a life-saving drug, but a life extending drug i.e. in case of kidney cancer, the life of a patient can be extended by 4-5 years, while in case of liver cancer the life of a patient can be extended by about 6-8 months. The drug has to be taken by the patient throughout his lifetime and the cost of therapy is Rs.2,80,428/- per month and Rs.33,65,136/- per year.

6. **The Application and initial developments**

The Applicant filed an Application for Compulsory License (hereinafter referred to as the "Application") on 29.07.2011 under Section 84(1) of The Patents Act 1970 (hereinafter referred to as the Act) r/w Rule 96 of the Patent Rules 2003 (hereinafter referred to as the "Rules") in respect of the Patent No. 215758. The Applicant being a leading manufacturer and distributor of various drugs in India approached the Patentee with a request for a voluntary license to manufacture and sell the drug, which did not materialize. The Applicant proposed to sell the drug at a price of Rs.8800/- for one month therapy as compared to the price of about Rs.2,80,428/-, which was being charged by the Patentee at the time of making the Application. Three years had lapsed since the date of grant of patent when the Application was filed. The Applicant is also a *person interested* within the meaning of the Act. Upon arriving at a conclusion that a *prima facie* case under Section 87(1) of the Act has been established, vide order dated 9.8.2011, the Applicant was directed to serve a copy of the Application upon Patentee and the Application was published in the official journal published on 12th August, 2011. On 23.08.2011, the Patentee filed a request seeking an extension of time by one month to file the notice of opposition and the same was allowed

in the interest of justice. The Patentee then filed an 'interlocutory petition' dated 07.10.2011 seeking stay in this matter on the ground that an infringement suit was pending before the Hon'ble High Court of Delhi against the Applicant w.r.t. the same Patent. The request of the Patentee was refused vide order dated 27.10.2011. The Patentee filed a petition seeking extension of time to file a review petition and another petition for staying the proceedings on the ground of pendency of a contempt petition against the Patentee in the Hon'ble High Court of Delhi. Both the petitions were refused vide my order dated 21.12.2011.

Meanwhile, the Patentee preferred Writ Petition No. 2194/2011 in the Hon'ble High Court of Judicature at Bombay challenging the said Order dated 9.8.2011. The Writ Petition was disposed of by the Hon'ble High Court of Bombay with the following order dated 11.11.2011:

"Considering the said aspect of the matter, the above petition is not entertained by this Court, with a liberty to the petitioner to file appropriate petition before the Delhi High Court, especially when it has been observed by the Delhi High Court in Injunction Application No.7343 of 2011 that in view of the pendency of the application before the Controller of Patent, both the parties agree not to proceed further with the present proceedings. Considering the said aspects, the above petition is disposed of with a liberty to the petitioner to move the Delhi High Court regarding the subject matter. Time to file reply before the Controller of Patent is extended till 18.11.2011. Such extension is given without prejudice to the rights and contentions of the parties and with a view to see that the petitioner in the meanwhile, can approach the Delhi High Court by way of appropriate proceedings. It is clarified that we have not expressed any opinion on the merits of the case and the points raised by both the sides in this petition are explicitly kept open."

The Patentee thereafter exercised his constitutional right by approaching the Hon'ble High Court of Delhi by way of Writ Petition

No. 8062/2011, thereby challenging the aforementioned order dated 9.8.2011. The Hon'ble High Court of Delhi disposed of the said Writ Petition with the following order dated 16.11.2011:

"The petitioner impugns the order dated 11.08.2011 passed by the Controller of Patents, Patent Office, Mumbai in C.L.A. No.1 of 2011. It has been pointed out to learned senior counsel for the petitioner that the impugned order merely records a prima facie view that a case under Section 84(1) of the Patents Act has been established. The petitioner is still entitled to contest the said proceedings before the Controller of Patents.

Learned senior counsel for the petitioner submits that before arriving at the said prima facie view, the Controller of Customs has not conducted any enquiry and not recorded any evidence. It shall be open to the petitioner to raise all such pleas before the Controller of Patents in answer to the notice. In view of the aforesaid, the petitioner wishes to withdraw this petition. The petition is accordingly dismissed as withdrawn."

Subsequently, the Patentee filed a notice of opposition on Form-14, along with evidences and the conditions for license, under Section 87(2) of the Act read with Rule 98(1) of the Rules on 18.11.2011, within the timeline as extended by the Hon'ble High Court of Bombay.

7. **Hearings**

The parties were heard on 13.01.2012. During the course of hearing, counter allegations were raised by both the parties that evidence has not been filed on affidavits. The parties were also informed by me during hearing that the evidence filed by both the sides are not conclusive and that there is a need to lead further evidence on crucial aspects to assist the tribunal in arriving at a conclusive finding. Parties agreed to the same. Accordingly, in the interest of justice, leave was granted for filing further evidence to both the parties and the

matter was adjourned to 27th March 2012. Both the parties were given full opportunity to present their side of the case. As the hearing could not be concluded on 27th March, 2012, the same was continued on 28th March 2012, on which day the hearings were concluded.

8. **Preliminary issues raised by the Patentee and decision thereof**

a. On the first day of hearing, the Patentee submitted that the Applicant has specifically raised only the ground mentioned in S.84(1)(a) of the Act and has failed to mention the grounds enumerated under S.84(1)[(b) and (c)] of the Act. This objection appears to be of a hyper-technical nature as it is found that in the Application all the grounds mentioned in S.84 of the Act have constructively been raised by the Applicant and must accordingly be adjudicated.

b. The Patentee also contended that the provisions of Section 84(6)(iv) have not been satisfied and that the Application is required to be rejected on this ground alone. The Patentee's contention is that from the tenor of the letter dated December 6, 2010 sent by Applicant seeking voluntary license, it appeared that the Applicant was fulfilling the requirements for filing an Application for compulsory license. Accordingly, this letter cannot be termed as an effort on reasonable terms and conditions. The Patentee further contended that the Applicant failed to mention any terms and conditions that he was willing to accept. Furthermore, the Patentee states that the Applicant was given a time of 14 days to return if he had anything to say.

I am of the view that the Applicant could have been more humble in writing the said letter dated December 6, 2010 so as not to hurt

the sensitivities of the Patentee. Patentee, vide Para 9 of the reply stated as follows:

'In view of what has been stated above, our client does not consider it appropriate to grant voluntary license to manufacture and market the product, Nexavar to NATCO.'

As the Patentee categorically refused to grant a voluntary license, I don't think that the Applicant could have taken further efforts for grant of a voluntary license. Hence, I am of the view that the requirements of Section 86(4)(iv) have been satisfied.

c. The Patentee raised a further objection that the Controller's order dated 09.08.2011 was erroneous as the Applicant did not make out a *prima facie* case and the Controller ought not to have passed an order under Section 87(1) of the Act, without first giving an opportunity to the Patentee to be heard in the matter. It was also argued that this violates the basic principle of natural justice as no *prima facie* case was made out (without there being any evidence) and the Patentee ought to have been given an opportunity to point that out and show the Law on the point of natural justice.

In this regard, while considering the Application, the Form-27 filed by the Patentee was also considered by me. As per the Form-27 submitted by the Patentee, I found that in 2008 the Patentee did not import the drug at all, while in 2009 and 2010 the Patentee imported in small quantities. The quantities imported by the Patentee *prima facie* appeared to be grossly inadequate. In view of this and the submissions made by the Applicant in his Application, and on satisfaction that a *prima facie* case has been made out, an order under Section 87(1) of the Act was passed. The Act does not envisage a hearing for the Patentee while issuing an order Section 87(1), particularly in view of the fact that no right, title or interest

of the Patentee is affected by the said order and also because unnecessary delay is not in the interests of public. However, that does not in any way mean that the patentee is prejudiced. The Act affords full opportunity to the Patentee to present his case in the best possible manner, before any order affecting his right, title or interest is passed. Accordingly, I find no force or substance in the submissions of the Patentee that before passing the said order, which merely records a *prima facie* satisfaction of the Controller, an opportunity of hearing should have been granted to the Patentee and this issue is decided accordingly.

d. The Patentee raised a contention that the Applicant has suppressed the fact that M/s. Cipla, another generic drugs manufacturer in India, has been selling the generic version of the drug Sorafenib in India since April-May 2010. This suppression of fact by the Applicant shall entail rejection of the Application on this ground itself. The Applicant replied to this contention and submitted that they were aware of the alleged infringing sale by M/s. Cipa and that the Patentee has filed a infringement suit against M/s. Cipla, which is pending. The Applicant further argued that the failure of the Patentee to discharge his obligations under the Act has led to this Application. The presence of Cipla is not a material consideration so far as this Application is concerned as the alleged infringing sale by Cipla cannot rescue the Patentee and hence there has been no material suppression of any relevant fact. I find merit in the Applicant's pleadings and hence there is no ground for rejecting the Application on this ground. However, the other arguments made by the Patentee relating to sales of M/s. Cipla will be discussed later in the relevant paragraphs below.

9. **Main issues to be decided in the case**

Now I proceed to dwell upon the pleadings by the Applicant and Patentee on the three substantial issues in this Application [Section 84(1)(a, b and c)], i.e. whether,

a. the reasonable requirements of the public with respect to the patented invention have not been satisfied.

b. the patented invention is not available to the public at a reasonably affordable price.

c. the patented invention is not worked in the territory of India.

I will take up the afore-mentioned grounds one by one through consideration of the pleadings by parties, appreciation of evidence on record and my decisions thereof.

10. **Reasonable requirements of the public.**

Section 84 of the Act states as follows:

"84. Compulsory licenses. –

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied.....'

Applicant's submissions

The Applicant has made the following submissions through pleadings and by way of written arguments along with evidence on affidavits. Applicant's submissions in brief are as follows:

a. The reasonable requirements of public have not been fulfilled with respect to Patent No. 215758. As per the data gathered and published in GLOBOCAN 2008 (a publication by GLOBOCAN project of the World Health Organization), the approximate patient base in India, in case of liver cancer is about 20000 (14516 men, 5628 women), while in case of kidney cancer the patient base in India is about 8900. In India, in 90% of the patients, the disease of liver cancer is detected at a late/advance stage. Hence, assuming that 80% of the patients in liver cancer alone require Sorafenib, 16,000 patients having liver cancer are eligible for Sorafenib. Similar is the case with kidney cancer. When one compares the demand with the working statement (Form-27) filed by the Patentee a clear picture of the demand not being met clearly emerges:

	Total Patients	**Demand for 80% of patients**	**Bottles per month (required)**	**Bottles Imported in 2008**	**Bottles Imported in 2009**	**Bottles Imported in 2010**
Liver Cancer	~ 20,000	~ 16,000	~ 16,000	-Nil-	~ 200 bottles	Unknown
Kidney Cancer	~ 8,900	~ 7,120	~ 7,120			

b. Patentee imports and sells the drug in India and has not taken adequate steps to manufacture the product in India to make full use of the invention. The drug is exorbitantly priced and out of reach of most of the people. The product is available only in limited quantities. It is available in pharmacies attached to certain hospitals and that too only in metro cities such as Mumbai, Chennai, Kolkata and Delhi. The product is often out of stock or not available in common pharmacies even in metro cities. The product in question is not a luxury item but a life saving drug and it is highly important

that substantial part of the demand be met strictly. In the present case, even 1% of the public does not derive benefit of the patented drug.

c. The Patentee received FDA approval for the product in 2005 and launched the same in the world market around 2006. The sales figures for the years 2006-2011 obtained from public records show that the Patentee not only launched the product all over the world in 2006 but made thumping sales which has grown by leaps and bounds every year.

Sales figures of the drug:

	2006	2007	2008	2009	2010
Sales per year (Worldwide)	$165m	$371.7m	$677.8m	$843.5m	$934m
Sales in India	Nil	nil	Nil	16 crores	unknown

These figures clearly demonstrate the neglectful conduct of the Patentee as far as India in concerned. It shows that although the Patentee has fully developed and launched the product in various parts of the world and reported sales atleast since 2006, and despite the fact that the Patentee had filed its application in India in 2000, the Patentee clearly neglected India and did not launch until 2009. The Patent was granted in 2008 and from then till 2011 the Patentee did not bother to fulfill the demand to comply with the duty imposed by the Act.

d. The Patentee only imports the drug into the Indian market and does not manufacture the drug by itself in India, though it does manufacture and sell other products in India. The worldwide sales in various countries over the last three years has exceeded USD

2454 million whereas in India the sales did not exceed USD 32-40 million.

e. On the Patentee's submission that CIPLA entered the market with an infringing product, which was priced at about Rs.30000 against the Patentee's price of Rs.2,80,000, and this has undercut his market share thereby preventing him from selling in sufficient numbers. The Applicant submitted that the presence of Cipla in the market is irrelevant since:

   i. The demand in the market for the drug Sorafenib has to be fulfilled by the Patentee and not by the third parties; the sales by Cipla are not reflected in the working statement filed by the Patentee nor in the annual returns filed by the Patentee which clearly reflects the fact that Cipla's sales are of no relevance;

   ii. Cipla faces a suit for injunction and its sales are that of an infringer which cannot be taken into account;

   iii. Cipla could be injuncted anytime and the supply by Cipla may stop totally. Public cannot be held to ransom or left at the mercy of such uncertain supply.

Further, the mandate of law is not just to supply the drug in the market but to make it available in a manner such that substantial portion of the public is able to reap the benefits of the invention. If the terms are unreasonable such as high cost of Rs 2,80,000/-, availability is meaningless.

f. Availability of the drug is not to be measured in terms of mere Field Force or field strength of the Patentee. If the drug is so highly priced that the ordinary public cannot afford it, then it is a fact that the product is not available to the public on reasonable terms and

presence of an army in the field is of no consequence and such high price becomes a barrier to availability of the drug, which is precise evil that the legislation is designed to curb.

The number of patients and the actual demand for the drug far exceeds the supply thereof by the patentee. Furthermore, price of the patented product is too high and simply unaffordable by the common man making the product inaccessible and out of reach. Hence, the demand for the patented product has not been met on reasonable terms.

In view of the above, the reasonable requirements of the public with respect to the patented invention have not been satisfied and this makes out a fit case for the grant of Compulsory License.

Patentee's submissions

The Patentee has made the following submissions through pleadings and by way of written arguments along with evidence on affidavits. Patentee's submissions in brief are as follows:

a. Estimated incidence for kidney cancer in India as per GLOBOCAN 2008 is 8900 patients and mortality is 5733 patients, which accounts 64.4% of total patients. Of the 8900 patients of kidney cancer around 90% account for RCC, which equals to approximately 8010 patients.

Around one third (33.33%) of the initially diagnosed RCC patients are affected with the stage IV disease (33.33% of 8010= 2669). This means there are approximately 5341 stage I, II, III patients, and about **2669** stage IV patients. In 25% of patients having surgical resection for localized disease (stage I, II and III) with a curative intent, recurrence occurs (25% of 5341= 1335). These **1335** patients (from stage I, II and III) eventually may progress to

stage IV RCC. Therefore, the total number of patients falling under stage IV of RCC is approximately 2669 + 1335 = 4004 patients. Therefore, the total number of patients with RCC, entitled for treatment with the drug is approximately **4004**.

Hepatocellular Carcinoma (HCC) is classified into early, intermediate, advanced and terminal stage. As per the HCC trials conducted globally, the drug is used in advanced cases of HCC. Therefore, in practice it is being used in advanced HCC based on the available global clinical trial data.

Estimated incidence of HCC in India as per GLOBOCAN is 20,144 patients and mortality is 18043 patients which accounts 89.5% of total patients. Approximately 24% of the patients are in advanced stage of HCC, which require systemic treatment like sorafenib. (This accounts to approximately 4,838 patients out of 20144 total HCC patients.) Therefore, the total number of patients of HCC entitled for treatment with the drug is approximately **4838**.

The total number of patients eligible for the drug are 4004 (RCC) and 4838 (HCC) i.e. a total of **8842**. Alternative treatments are also available to the patients and the Applicant has not agitated this fact.

b. The Applicant has provided misleading statistics and a list of cities that are covered by Field Force and Distributors and the list of cancer treatment centers in India has been provided as Annexure-4 to the Notice of Opposition. On perusal of the said annexure, it is evident that the Patentee's Field Force and Distributors do cater to all the cancer treatment centers in India. In addition, the following procedure is followed by the Patentee to ensure that the drug is available wherever it is required:

   i. Distributors supply to hospitals, pharmacies, retailers and patients.

ii. Distributors supply to outstation towns, cities where the drug is required.

iii. For outstation patients, supply is done through courier.

c. Further, the treatment with the drug should be supervised by Doctors who have experience of anticancer treatments (Oncologists). Hence, the allegation of the Applicant that it is not available in villages is of no consequence as it has to be made available in cancer hospitals and institutes, which duty the Patentee has duly performed. Further, it is available at 50 places in 278 hospitals and institutes. Hence, the drug is accessible to the public at large.

In view of the above, the issue of requirement vs. availability is being appropriately taken care of by the Patentee.

d. The Applicant has erroneously and impermissibly linked the issue of price of the drug to this ground i.e reasonable requirements of the public have not been satisfied. Section 84(7) of the Act clearly lays down as to when the reasonable requirements of public shall be deemed not to have been satisfied. It was further submitted that none of the deeming provision under Section 84(7) relates to the price of the drug or availability to the public at a reasonably affordable price, which is a ground under Section 84(1)(b) of the Act.

e. The purpose behind Section 84(1)(a) is to enhance access to patented inventions. However, access to a patented invention is not identical to affordability thereof and cannot be on the identical footing. For example, for access to medicine, existence of trained healthcare staff and infrastructure, cultural acceptability of treatment, accessibility of healthcare facilities, quality of care and insurance facility all play a role in access. In other words, the

parameters/criteria of establishing accessibility or lack thereof and affordability or lack thereof are different. The aforesaid submission is further strengthened by the fact that the Patents Act provides two different/specific grounds Section 84(1)(a) [lack of accessibility] and Section 84(1)(b) [lack of affordability] for the grant of Compulsory License. As such, the aforementioned two grounds cannot be mixed as has been done by the Applicant in the present case. It has to be appreciated that the grounds are distinct and separate.

f. The Patentee in their affidavit submitted through Dr. Manish Ram Mohan Garg, Country Medical Director, that the availability of the drug in India has been considerably enhanced due to its sale by M/s. Cipla. The affidavit reveals the following table of sale by M/s. Cipla and the Patentee during the year 2011:

	Q1A	Q2A	Q3A	Q4 E*	Total
Cipla No. of boxes	532	1071	1358	1725	4686
Growth %		101	27%	27%	
Bayer boxes	119	179	138.5	157	593

*projected for Q4 based on growth trend of last quarter.

The Patentee submitted further data in the form of table through the affidavit giving projections of sales by them and M/s. Cipla upto the year 2015.

	2011	2012	2013	2014	2015
Total No. of Patients (Cipla + Bayer)	3908	4844	6034	7544	9463
Total No. of HCC + RCC patients eligible for Sorafenib	8842	8842	8842	8842	8842
	44%	55%	68%	85%	107%

Based on the above figures, the Patentee argued that the reasonable requirements of the public is being fulfilled by Patentee and M/s.Cipla cumulatively currently and will be fulfilled in future as well. Hence, there exists no case for grant of compulsory license under Section 84(1)(a).

Decision

I have carefully gone through the pleadings of the parties, the affidavits, oral as well as written submissions, and the relevant provisions of the Act. The Applicant has relied upon the GLOBOCAN 2008 for the incidence of Liver and Kidney Cancer in India. The Patentee too has extensively referred to the same statistics. In the absence of any other evidence on record as to the incidence of the two types of cancer, I am constrained to accept the statistics available in the GLOBOCAN 2008 and the projections of incidence given therein.

Patentee by his own logic has derived a figure of number of patients who are eligible for this drug to be around **8842.** The Applicant submitted that both these cancers are generally diagnosed in India at an advanced stage. Given the state of healthcare infrastructure in the country and the income level of its people, I find merit in the argument of the Applicant. I am accordingly of the view that the number of patients requiring treatment by this drug will be much higher than the figure derived by the Patentee.

I am not inclined to accept the argument of the Patentee that the sales of Patentee combined with that of M/s. Cipla satisfy the reasonable requirements of the public. The Application for a compulsory license is filed against the Patentee or his licensee, if any, and it is their conduct that is relevant in this case. The conduct of any

other person, especially an alleged infringer, cannot by any stretch of imagination be considered in this case. This view flows from Section 86(6)(i), which states as follows:

"In considering the application filed under this section, the Controller shall take into account, -

(i).....the measures already taken by the patentee or any licensee to make full use of the invention;"

If the conduct of the Patentee is considered with reference to this provision, it follows that the Patentee tried his best to prevent M/s.Cipla by preferring an infringement suit against them, which is at an advanced stage. In such circumstances, the Patentee appears to be indulging in two-facedness by adopting one stand before this tribunal and another stance before the Hon'ble High Court of Delhi, in order to defend the indefensible.

M/s.Cipla is an alleged infringer, as per patentee's own submissions, and accordingly cannot discharge the obligations of Patentee under the Act. The Patentee appears to have treated M/s.Cipla, in this case, as if they are their licensee. M/s. Cipla may be injuncted at any time by the Hon'ble Court. Such an uncertain supply by an alleged infringer cannot be considered while deciding this matter, as it involves the lives of cancer patients, which in my opinion cannot be left to the uncertainties of legal proceedings.

The Patentee has submitted an affidavit of Dr. Garg and has submitted a patient coverage during 2011. It is pertinent to mention that the Patentee refrained from giving the patients covered by his drug and simply submitted a patient coverage by him and M/s.Cipla together. It is noted that the Form-27 for 2009 filed by the Patentee does not provide any logical information about the sales. Form-27 for the year 2010 discloses that the Patentee did not import any 'sale pack'

but imported only 340 units [60 tablets pack] of 'support pack' and 340 units [60 tablets pack] of 'sample pack', both having an 'invoice value' of Rs.10,045,692. It appears to me, from the Form-27 filed by the Patentee for the year 2009 and 2010, that only an insignificant quantum of the drug was made available by the Patentee to the public during these two years. As discussed above, I am not inclined to buy the argument of the Patentee by taking shelter of M/s. Cipla's supply.

The Patentee has arrived at a figure of 8842 cancer patients according to his logic and has compared this figure with the combined sales achieved by him and M/s.Cipla. The Patentee has submitted that they have sold about 593 boxes during the year 2011. It is an admitted fact that a liver patient's life is extended by 6-8 months and a kidney cancer patient's life is extended by 4-5 years upon treatment with the drug. Even if I consider that on an average a patient requires three packets (3 months), the patentee would not have supplied the drug to more than 200 patients in 2011. By his own admission, the Patentee has submitted the number of patients eligible for Sorafenib is 8842 per year. Hence, the Patentee has made available the drug only to a little above 2% of the eligible patients. The Applicant submits that the annual requirement of the drug is about 70000 boxes.

From the conclusions drawn about the probable number of patients requiring the drug, the annual requirement could lie between 9000*3=27000, which is the Patentee's figure, and 70000 boxes per annum, which is the Applicant's figure.

For argument sake, even if I consider the sale 4686 packets during 2011 by M/s.Cipla, the supply in India was not anywhere near the requirement.

In the aforementioned circumstances, the Patentee's conduct of not making the drug available as per the requirements of public in

India during four years, since the grant of Patent, is not at all justifiable. This is inspite of the fact that the Patentee was already marketing the drug in other parts of the world from 2006 onwards. It is not the case of the Patentee that he had to develop the drug before launching the same in the Indian market or had no means to market the drug. The Patentee has a considerable Field Force and Distributors, being an old and established force in the Indian market. In the year 2009, the sales of Patentee in India were only Rs.16 Crores, as per the Applicant, which appears to be incorrect as the Form-27 filed by the Patentee for the year 2009 discloses a possible sale of Rs.2 Crores only. It is also not the case of the Patentee that there is no demand for the drug because as per their own submission, there is a requirement for at least 8842 patients. Even after the lapse of three years, the Patentee has imported and made available only an insignificant proportion of the reasonable requirement of the patented product in India.

It is also pertinent to refer to Section 84(7) of the Act, which states as follows:

"(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied –

(a) if, by reason of the refusal of the patentee to grant a license or licenses on reasonable terms, –

.....

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or....."

In the circumstances of this case, it is also clear that Section 84(7)(a)(ii) in invoked beyond doubt. Accordingly, I hold that the reasonable requirements of the public with respect to the patented

invention have not been satisfied in this case and consequently a compulsory license be issued to the Applicant under Section 84 of the Act.

11. **Reasonably affordable price**

Section 84 of the Act states as follows:

"84. Compulsory licenses. *–*

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –

.....

(b) that the patented invention is not available to the public at a reasonably affordable price .....'

Applicant's submissions

Price of the patented product is too high and simply unaffordable by the common man making the product inaccessible and out of reach – hence the demand for the patented product has not been met on reasonable terms.

The Applicant submitted through the affidavit of Sh. C. Rammanohar Reddy, the Editor of Economic and Political Weekly that there are a number of ways for determining the affordability of a drug. These include the following two methods, as described in following published papers:

i. Shanti Mendis et al, "The availability and affordability of selected essential medicines for chronic diseases in six-low and middle income countries", [Bulletin of the World Health Organization, April 2007, 85(4)]:

As per this approach, the number of days a lowest paid government worker would be required to work to purchase from the public sector, a month's course of medicine at the standard or common dose, has to be considered. It has been argued that in the case of the present drug such a Government Worker would have to work for three and a half years to be able to purchase the drug at a price of Rs.2,80,000. By this time, going by that fact that the life-expectancy is not more than four months, such a government worker would not be able to afford it.

ii. Laurens M. Niens et al, "Quantifying the Improvershing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World", PLOS Medicine, August 2010, Volume 7, Issue8:

As per this approach, the author has opined that the impoverishment effect of the medicine should be considered i.e. the percentage that would be pushed below a certain income level when having to purchase the medicine. According to the official Government of India norms, a family of five with an income of more than Rs. 4805 (Rs.57,660 a year) in urban areas and more than Rs. 3924 (Rs.47,088 a year) in rural areas, is deemed to be above poverty line. At present an estimated 72% of the population is above this very low poverty line. Hence, a medicine that costs Rs.2,80,000 a month will push a large proportion of the population into poverty. It is also suggested that the price should be arrived at after taking into account the manufacturing costs, administrative expenses, taxes etc. and

should provide for a certain minimum profit which would incentivize a company to sustain manufacture and sale of the drug in the market.

Applicant has also submitted an affidavit by Mr. James Packard Love, Director, Knowledge Ecology International, a non-profit organization located in Washington DC, USA, and co-chair of the Trans-Atlantic Consumer Dialogue (TACD) Policy Committee on Intellectual Property Rights. It was submitted that Mr. James Love is an invited expert on intellectual property issues in meetings and consultations organized by the World Intellectual Property Organization (WIPO), World Health Organization (WHO), the World Trade Organization (WTO), the United National Program on Development (UNDP), the United Nations Conference on Trade and Development (UNCTAD), the UN Human Rights Council, the Hague Conference on Private International Law, the UNITAID, the World Bank and other multilateral and regional bodies. Mr. James Love has also served as an advisor to several national governments on Intellectual Property issues, including the Competition Commission in South Africa where he was the principal consultant to evaluate a complaint that the prices for AIDS medicines were excessive. It has been deposed that the World Bank estimates of Indian Gross National Income per capita for 2010 is $1330, which is approximately Rs.60,455. The present pricing of the drug shatters the notions of cost-effectiveness.

Bayer had received an FDA designation under the US Orphan Drug Act in 2004. The clinical trials that were related to the orphan drug indication, "treatment of renal cell carcinoma", were eligible for a 50 percent orphan drug tax credit, lowering the net cost of the investments to Bayer. There is no publicly available information on the

amount of tax credit received by Bayer. The credit was available during the period of the most extensive spending on clinical trials, and for the largest and most expensive trials that were undertaken. The issue of lack of transparency in the reported expenditures on R and D was also raised by Mr. James Packard Love. It has been submitted that while the outlays on research and development related to the drug were not trivial, the revenue from the sales were much larger. In 2006, its first year on the market, Onyx, with whom the Patentee entered into a drug development agreement, reported that in the year 2006, its first year on the market, the drug generated $165 million in sales, an amount nearly equal to all joint outlays on R and D from 1994 to 2004. In 2007, Bayer reported the sales of the drug as $371.7 million. By 2008, the sales were reported at $ 678 million, i.e. a total of $1.2 billion within three years of approval as an 'orphan drug'. It has been submitted that if the Patentee has raised the issue of R and D, then it must also open the doors to look at the revenues and profits from the drug. The deponent has also demonstrated as to how various methods can be utilized for calculating royalty.

In conclusion, the Applicant has submitted that the pricing adopted by the Patentee is exorbitant for its patented life-saving product and is an abuse of its monopolistic rights and such practice is unfair and anti-competitive and has requested for grant of a compulsory license on this ground.

Patentee's submissions

It was submitted that innovation based products cost a price over generics, but this price pays for the pipeline (i.e. the future innovation) and competition. The higher price of the drug covered by the subject patent as compared to generic version thereof is justified

inasmuch as for the Patentee, it also involves the Research and Development (R&D) cost of innovators as against the Applicant who merely copies the drug discovered by the Patentee thereby taking advantage of the R & D carried out by the Patentee.

The affidavit filed by Mr. Herald Dinter elaborately explains the complete process to discover and develop a drug. It has been explained that quite a large amount of money is spent in failed projects, which is about 75% of the total R & D cost. The marketed product must pay not only for its own R & D cost but also for the cost of the underlying failed R & D, and further must underwrite the additional R & D for the next generation of innovations. The Patentee and its collaborator continue to invest major sums into further development of Sorafenib. Its potential for treatment of cancers, other than renal and kidney cancer is under investigation in large Phase III trials (e.g. breast cancer, thyroid cancer and non-small-cell-lung cancer). It is therefore important to understand that R & D on a new drug does not at all stop when the drug is launched in the market but actually continues with considerable investments. In conclusion, it is neither possible nor – if it were somehow possible – would it be reasonable to look at past R & D expenditure for a launched product to decide whether its current price is reasonable. Rather one has to take into account the total R & D spending of a company and the need and desire to finance such R & D sustainably to ensure ongoing innovation in healthcare. In 2010, the pharmaceutical division of Bayer invested almost € 1.8 bn or 16% of its net sales into R & D for pharmaceuticals, and 6200 employees worked in the R & D divisions of Patentee globally. Since, the year 2007, the cumulative R & D spending of Patentee was € 8 bn. In this period, 2 NMEs and one new combination

product were brought to the market. It thus takes investments of more than €2 bn to bring an NME to the market.

It was submitted that Nexavar has been granted an 'orphan drug' status in the US and Europe. The exact criteria to meet the orphan drug status vary between jurisdictions. In the US, for example, Nexavar was granted 'orphan drug' status on the basis of having fewer than 200,000 patients for each of its indications. In Europe, one of the criteria for a drug to qualify for an orphan designation is that it must be intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting no more than 5 in 10,000 people in the EU. Therefore, the number of patients for cancer drugs (especially for orphan cancer indications as in the present case of Nexavar) is small when compared to the overall R & D investment of the originator. Further, if one compares this drug vis-à-vis other Oncology brands of innovation based companied, it will be found that the pricing is similar to other comparable drugs.

The Patentee desires to sustainably fund further research in areas of unmet medical needs, which research is in public interest. Replacing the innovation based product with a generic will damage India and Indian patients in the long run as the Patentee as an originator provides more than just the drug product, e.g., education of practitioners on use of the product, pharmacovigilance (observing/evaluating/improving the safety of medicines) etc.

It is the Patentee, being the innovator and having invested resources in developing/marketing the innovation based product, who would decide as to what would constitute a "reasonably affordable price" for such product. It needs to be appreciated that if a higher price of the patented drug with huge investment in R & D by an originator is a good enough argument for the Applicant to request for the grant of

Compulsory License, it will always be applicable and will always circumvent the objective of the Patents Act, which cannot be the intention of the Legislature.

Patents Act provides that the patented invention should be available to "public" at a "reasonably affordable price". "Reasonable" must mean "reasonable" to the public i.e., patients and the patentee as well. If it is not read in this manner, the word "reasonable" would not have been present there. Balance needs to be created. Therefore, the cost of R&D and the cost of manufacture, both have to be taken into account while determining "reasonable affordable price".

There can be no "reasonably affordable price" below the expense incurred in the development of the product and the cost of manufacture is a reasonable element of commercial gain. "Reasonably affordable price" has to be used to balance the interest of the consumer/public without compromising on the interest of the innovator. "Reasonably affordable price" does not relate to the lowest price relative to the cost of manufacturing alone. "Reasonably affordable price" must necessarily take into account the cost of R&D and reasonable gain.

"Public" denotes different sections of public. "The Rich class", "the middle class" and "the poor class". A blanket CL cannot be granted thereby giving the opponents patented drug to all sections of "public" at the same price. Therefore, a method will have to be devised in order to make it "reasonable" for the patentee and to make it "reasonably affordable" for the different sections of "public".

"Treating unequal as equal" is discriminatory and is not permissible under law. Placing "the rich class" and "the lower class" in one category at the expense of the patentee is unreasonable and cannot

be the intention of the legislature. In case of a drug, if R&D is not to be killed, this device has to be implemented.

The word "reasonable" necessarily mean affordable to patients, which necessarily is relative *vis-à-vis* to the paying capacity of the patient. "Reasonably" means "reasonable" to the patients and patentee as well. The Patents Act does not envisage the grant of CL unless the product is not reasonably affordable. It will be within the jurisdiction of the Controller (implied power) to reject, resurrect or keep in abeyance an application for the grant of CL if the patentee is willing to meet the "reasonable requirement" and provide the patented product at "reasonable affordable price to the public". It cannot be the intention of the legislature to lower the price for those patients who can afford the opponent's drug. "Reasonableness" is a relative term which has to be interpreted in the circumstances of each case.

The term "affordability" is the capacity to pay. Different classes/sections of the public have vastly different capacity to pay. What may be "affordable" for one class/section may not be "affordable" to another class/section. The phrase "available to the public at a reasonable affordable price", therefore, must be interpreted to mean as to whether the treatment is "affordable" to a particular class/section of public. Therefore, in modern times, one of the means whereby the treatment can become "affordable" is by way of insurance cover. In other words, treatment as a whole is "affordable" including the drug (being one of the factors of treatment) by an insurance cover. Therefore, "affordability" has to be judged from the cost to be incurred on the insurance cover. Question now that arises for consideration is not whether the patient can afford the drug at a given cost but whether the patient can afford the insurance cover. "Affordability" is also

required to be judged as to whether the patient can afford insurance cover.

In India, insurance cover is accessible to any person by the following modes:

(1) Voluntary health insurance schemes or private-for-profit schemes;

(2) Employer-based schemes;

(3) Insurance offered by NGOs / community based health insurance, and

(4) Mandatory health insurance schemes or government run schemes (namely ESIS, CGHS).

In the affidavit of Mr. Pradeep Kumar Sharma, Business Unit Head, Specialty Medicine, it has been stated that the New India Assurance Company Limited (NIA) offers an insurance policy which is extremely cheap as compared to general health insurance policies. Two such policies are currently offered by NIA and the maximum sum insured is of Rs. 75000 for the first policy and Rs. 3,00,000 for the second policy. A policy offered by ICICI Prudential secures coverage of Rs. 10 lakhs.

It was submitted that "reasonably affordable price" is the notional price, which has to be determined, and it cannot be obviously lesser than the royalty if fixed under Section 90 (1) (i) and (ii) of the Patents Act.

a. The application for Compulsory License must establish that the drug is not available at "reasonably affordable price". If it is available at "reasonably affordable price", a CL cannot be granted. It is a condition precedent, sine qua non for an application for grant of CL to be adjudicated upon. The applicant has chosen to show that the opponent's drug at Rs. 280,000 per month is not "reasonably affordable price" and has suppressed the fact that

Cipla's same drug is available to public approximately Rs. 30,000 per month.

b. The very bulk of sales of Cipla's drug at approximately Rs.30,000 itself is an evidence to show that it is at least "reasonably affordable price" for those patients who cannot afford the opponents' drug at its original price. The application is laible to be dismissed on this ground alone.

c. The CL ought to be dismissed at as threshold as the Applicant has been guilty of suppressing the fact that Cipla's product was available in the market which is a material fact to adjudicate upon the core issue involved vis-à-vis "reasonable affordable price". The suppression of material fact is a fundamental flaw and is certainly not an innocent one. The Applicant ought to have compared its price with Cipla's price and determined as to how Cipla's price is not "reasonably affordable price". The core issue before the Learned Controller is that Cipla's drug at its quoted price is not a "reasonable affordable price". The pleading of the Applicant is completely silent on this issue. Accordingly, the Applicant has failed to discharge the burden and therefore, the Learned Controller should use the discretion in favour of the patentee/ opponent in rejecting CL application. This fact was well within the knowledge of the applicant and inspite it chose not to disclose the said material fact thereby approaching the Learned Controller with unclean hands. It is further submitted that the motivation for the applicant appears to make a quick profit at the expense of the opponent's R&D.

d. It is submitted that in the absence of an injunction from Hon'ble Delhi High Court in CS (OS) No. 523 of 2010, Cipla is another entity apart from the opponent in the market selling the product

covered by the Subject Patent for Rs 27,960. It is further submitted that it is the case of the applicant that the demand of Nexavar is not being met as it is not available to public at "reasonably affordable price". The provisions regarding CL no-where mention that demand is required to be met by only the patentee.

Patentee has further submitted that the intention behind Chapter XVI of the Patents Act is that the patentee should not be allowed to charge exorbitant price so long as it is making a reasonable profit. There is no *suo motu* power upon the Learned Controller to grant CL. It is only upon an application made by "any person interested", that the Learned Controller may grant CL. Emphasis in this regard is laid on the word "may" appearing in Section 84 (4) of the Patents Act, the Learned Controller has a discretion as evident from the said provision. Further, it is submitted that Section 90 (1) (i) of the Patents Act is important in construing "reasonable affordable price". It is submitted that law does not envisage the grant of CL unless the hurdle/condition under the said clause is crossed. The cost of R&D that the patentee has incurred has to be taken into account while fixing royalty. It has no relationship whatsoever with the fact that patentee has already earned/ profited so much on Nexavar as has been the case of the applicant. The "reasonable affordable price" cannot be less than the royalty to be fixed by the Learned Controller. "Reasonable affordable price" does not merely depend upon the purchasing power of the public. It will have to be determined on the basis of cost incurred by the patentee on the R&D with some reasonable gain/profit to it. It is submitted that the affidavit of Mr. James Love does not further the case of the applicant as if his deposition is accepted, every time an application for CL will be filed, the Learned Controller shall call for the balance sheets of the patentee. That can certainly not be the intention of the legislature. In

any event, it is admitted case of the applicant that even its quoted price is too high.

Decision

I have carefully gone through the pleadings of the parties, the affidavits, oral as well as written submissions, and the relevant provisions of the Act to decide on the issue as to whether the patented invention is not available to the public at a reasonably affordable price in this case.

The Patentee has vehemently argued on 'reasonably affordable price' and has suggested that reasonableness has to be judged with respect to public as well as to patentee. The Applicant has argued that the 'reasonably affordable price' has to be interpreted as reasonable to public. Both the parties have also submitted that 'reasonably affordable price' is a notional price and has to be arrived at from the facts and circumstances on a case by case basis. Patentee has also argued that the sales made by M/s.Cipla at a price of about Rs.30000/- is a relevant factor to be considered in this case. Patentee also submitted that affordable to public is required to be considered as affordable to different classes/sections of public. On this point, I fully agree with the Patentee. I only wonder why the Patentee did not execute this concept by offering differential pricing for different classes/sections of public in India. Further, the Patentee in their affidavit submitted that they offer this drug at a similar price (subject to variation in exchange rate etc.) to patients all over the world.

As I have already decided that the sales by M/s. Cipla cannot be considered in these proceedings, I need not further dwell upon this issue. While deciding this case, I need to only decide as to whether the drug was available to the public at a reasonably affordable price or not.

I do not fully agree with the submission of Patentee that reasonably affordable price has to be construed with reference to the public as well as patentee. I am of the view that reasonably affordable price has to be construed predominantly with reference to public. Given the 'admitted facts' in this case, I need not go into these issues in detail as the admitted facts fully enable me to decide this issue.

As concluded in 10 above, during the last four years the sales of the drug by the Patentee at a price of about Rs.2,80,000/- (for a therapy of one month) constitute a fraction of the requirement of the public. It stands to common logic that a patented article like the drug in this case was not bought by the public due to only one reason, i.e. its price was not reasonably affordable to them. Hence, I conclude beyond doubt that the patented invention was not available to the public at a reasonably affordably price and that Section 84(1)(b) of the Patents Act, 1970 is invoked in this case. Consequently, a compulsory license be issued to the Applicant under Section 84 of the Act.

12. **Patented invention not worked in the territory of India**

Section 84 of the Act states as follows:

"84. Compulsory licenses. –

(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely –

.....

(c) that the patented invention is not worked in the territory of India.'

Applicant's submissions

The patented product is being imported into India and hence the product is not worked in the territory of India to the fullest extent that is reasonably practicable. As per the Act, the law expects the Patentee to work the invention in the country to the fullest extent possible. The provision of 'working' is to be read in the context of principles stipulated under Section 83[(a) and (b)] of the Act and with reference to the debates in the Lok Sabha.

It is pertinent to note that Patentee has been working the Patent in other countries since 2006; however, the Patent has not been exploited in India and no reason has been ascribed for such neglect. This is especially in view of the fact that the Patentee claims to have manufacturing facilities in India for several products, including Oncology products. As such there is no hurdle preventing the Patentee from working the Patent in India. A comparison of the working statement with the Patient base would clearly show that the Patent has not been worked in India.

Patentee's argument that even minimal working would satisfy the requirements of Section 84(1)(c) is flawed and fallacious for the reason that the expression "working" in Section 84 has to take color from Section 83(a). If the argument of Patentee were to be accepted then it would render Section 84(1)(c) otiose. As per Heydon's Rule, where two different interpretations are advanced, the one that suppresses mischief and advances the cause of the Act should be taken. Accordingly, the correct interpretation of Section 84(1)(c) would be that minimal working is no working at all and the invention must be worked to the fullest extent to escape from the rigours of Section 84(1)(c).

Patentee's submissions

The local working requirements in the Patents Act are directed towards ensuring that inventions are domestically "worked" i.e. supplied to the Indian market. An attempt to impose local working requirements – in the sense of local manufacturing – on patents granted in India would be beyond the scope of the Patents Act and against the intent of the legislature. The intent of the legislature is clear from the fact that the phrase "manufactured in India" was deleted from Section 84(7)(a)(ii) of the Patents Act during the amendment to the Patents Act in 2002, thus negating the requirement of local manufacture in order to make it consistent with Article 27(1) of TRIPS Agreement. This is also relevant to Section 84(7)(e) of the Patents Act, which states that a compulsory license should be available "if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article." Section 84(7)(e) should be interpreted, consistently with settled proposition of law, to apply where the patentee, or other entity claiming under the same right holder, was not supplying the patented product to the market.

The economies of scale ought to be appreciated which provides valid reason for not locally manufacturing the drug. Manufacturing of the drug requires huge investment in terms of infrastructure and logistics. Nexavar is a product of small global demand and hence is required to be produced in small volumes. With a view to achieving economies-of-scale with such a small-volume product and keeping manufacturing costs at a reasonable level, the Patentee made a strategic decision to consolidate both chemical API synthesis and pharmaceutical bulk production of the product covered by the Subject Patent within its manufacturing facilities in Germany. Further,

manufacturing bundled in Germany allows for maintaining a harmonized high quality production at reasonable manufacturing costs due to volume scale. In addition, production in Germany allows for taking advantage of good infrastructure for supplying global markets as good downstream and upstream industries ensure a smooth supply chain process. The quantities required in India do not economically justify setting up a manufacturing facility by Bayer in India. However, these can, due to the local nature of their sales, be manufactured on contract manufacturing basis with other manufactures who are expert in manufacturing those specific dosage forms.

The Patentee also submitted a detailed list of contract manufacturers (Annexure-6 of the Notice of Opposition). It is a settled proposition of Law that importation does indeed satisfy the working requirements mandated under the Patents Act.

Decision

I have carefully gone through the pleadings of the parties, the affidavits and oral as well as written submissions to decide the issue as to whether the patented invention is worked in the territory of India or not. The term 'worked in the territory of India' has not been defined in the Act. Hence, one has to seek its meaning from various International Conventions and Agreements on intellectual property, provisions contained in the Patents Act, 1970, the context in which this concept appears, and also the legislative history.

It appears that the arguments of the patentee referring to the deletion of the phrase 'manufactured in India' from Section 84(7)(a)(ii) by the Patents (Amendment) Act, 2002 are misplaced. In fact, the phrase was deleted from Section 90(a) of the unamended Patents Act, 1970 [hereinafter referred to as the 'erstwhile Act']. It may be noted

that Section 84 (7) is the corresponding provision under the existing Act [hereinafter referred to as the 'amended Act']. The Patentee argues that the legislature deleted 'default of the patentee to manufacture in India to an adequate extent and supply on reasonable terms the patented article' [hereinafter referred to as the 'concept'] from Section 90(a) of the erstwhile Act, to make the Patents Act, 1970 consistent with Article 27 of the TRIPS Agreement.

It is necessary to address this crucial argument of the patentee in detail. It is pertinent to mention that Section 90 of the erstwhile Act appeared in a different context, i.e. with reference to the issue of 'reasonable requirements of public'. The deletion of this concept was one face of the coin, which is being tossed by the Patentee to suit his convenience. However, there is another face of the coin, which is that this concept was removed from 'a context', i.e. 'reasonable requirements of public', and was made a separate ground for grant of a compulsory license under Section 84(1)(c), with a substantially altered scope.

It must be appreciated that this is not a simple case where a concept is removed from one place of an Act. It is in fact a complicated case where a concept is removed from one place of an Act and is incorporated at a different place, in a different context, and with a substantially altered scope. Accordingly, it cannot be said in such a straightforward manner that the intention of the Legislature, in removing the concept from Section 90(a) of the erstwhile Act, is to totally remove the concept of local manufacturing in India. In fact, this amendment has to be decoded by considering all the International Conventions and Agreements and the Patents Act, 1970 itself.

I have considered the Paris Convention, TRIPS Agreement and The Patents Act, 1970 in detail. Even though the TRIPS Agreement

marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO Members retained important policy options, flexibilities and safeguards, including the liberty to determine the grounds for issuing compulsory licenses. In addition, certain key terms relating to TRIPS obligations are not defined in the Agreement itself, which leaves considerable discretion to WTO Members as to how to apply the criteria within their national laws. The use of these policy options and other flexibilities can directly or indirectly help the low and middle-income countries to achieve a balance between intellectual property protection and specific developmental priorities, including the attainment of national public health objectives.

It may be noted that Article 2(1) of the TRIPS Agreement states that provisions of the Paris Convention shall be complied with by the member states. This implies that the Paris Convention is to be read as a part and parcel of the TRIPS Agreement. Article 5(A)(1) of the Paris Convention provides that importation of patented articles by the patentee shall not entail forfeiture of the patent. This would seem to suggest that importation could entail something less than forfeiture, such as a compulsory license. Such a conclusion is further fortified by the fact that Article 5(A)(2) of the Convention goes on to state that each member shall have the right to take legislative measures providing for the grant of compulsory licenses in order to prevent any abuse of patent rights, for example, failure to work. It is pertinent to note that the Paris Convention did not define the term 'working' and left it to the wisdom of Legislatures of member countries in a manner conducive to their socio-economic requirements.

Article 27(1) of the TRIPS Agreement, *inter alia*, states that "patents shall be available and patent rights enjoyable without

discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." When the Article 27(1) of TRIPS Agreement is read with the afore-mentioned provisions of TRIPS Agreement and the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory license is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility that the Parliament have invoked in Chapter XVI of the Patents Act, 1970 by incorporating a provision for grant of compulsory license upon failure to work the invention within the territory of India.

I now turn to the indications that the Patents Act, 1970 provides with reference to working of the patented invention. The Patentee contended that working means working on a commercial scale as is evident from Section 84(7)(e). It may be noted that while deciding 'the reasonable requirements of public', one relevant consideration, as provided under Section 84(7)(e), is that the 'working of patented invention in the territory of India on a commercial scale is being prevented by importation by the Patentee'. However, it must be appreciated that Section 84(7)(e) relates to Section 84(1)(a) and not Section 84(1)(c). Accordingly, it does not appear logical to me to accept the Patentee's contention that working means working on a commercial scale only as I find no such limitation in Section 84(1)(c). If such was the case, then there was no need to incorporate Section 84(1)(c) as a separate ground for grant of a compulsory license, as it would be an absurdity (emphasis added). Due to this, I am of the view that the term 'worked in the territory of India' cannot be restricted to

mean as 'worked in India on a commercial scale' only as submitted by the Patentee. To my mind, it is something more than that.

I now turn to Section 83, which is the over-riding legislative policy and the key to decoding the various provisions contained in Chapter XVI of the Act.

Section 83(b) states that Patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article. Upon a reading of this provision, it becomes amply clear to me that mere importation cannot amount to working of a patented invention.

Section 83(c) buttresses this interpretation by stating that the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Section 83(f), clears all ambiguity that the patent right should not be abused and the patentee should not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. Upon a combined reading of Section 83(c) and (f), it is clear to me that a patentee is obliged to contribute towards the transfer and dissemination of technology, nationally and internationally so as to balance the rights with the obligations. A patentee can achieve this by either manufacturing the product in India or by granting a license to any other person for manufacturing in India. Unless such an opportunity for technological capacity building domestically is provided to the Indian public, they will be at a loss as they will not be empowered to utilise the patented invention, after the patent right expires, which certainly cannot be the intention of the Parliament. Hence it follows that 'worked in the territory of India' implies manufactured in India to a reasonable extent so that the principles

enumerated in Section 83 can be brought into effect. In the absence of manufacturing in India, Section 83 will be a dead letter.

Another indication is provided by Section 84(6) and Section 90(2) of the Act, which state as follows:

Section 84(6)

"In considering the application filed under this section, the Controller shall take into account,—

.....

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;"

Section 90(2)

'.....no license granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad..... '.

The term 'work the invention' does not include imports as a compulsory license holder has to necessarily work the patent by manufacturing the patented invention in India. If, the licensee cannot import the product into India, for working the invention under the terms of License, barring exceptional circumstances mentioned in Section 90(3) of the Act, then is implies that importing cannot amount to working for a licensee. A combined reading of these provisions implies that the same logic must apply with respect to the Patentee as well.

From all the aforementioned indications, it is clear to me that the Paris Convention and TRIPS Agreement and Patents Act, 1970 read together do not in any manner imply that working means

importation. I am therefore convinced that 'worked in the territory of India' means 'manufactured to a reasonable extent in India'.

In the instant case, the Patent was granted in the year 2008. It is an admitted fact that the Patentee does have manufacturing facilities for manufacturing drugs in India, including Oncology drugs. However, even after the lapse of four years from the date of grant of patent, the Patentee failed to do so. The Patentee has also failed to grant a voluntary license on reasonable terms to anyone including the Applicant herein to work the invention within the territory of India. Accordingly, I hold that Section 84(1)(c) is attracted in this case and consequently a compulsory license be issued to the Applicant under Section 84 of the Act.

13. **Request for adjournment under Section 86**

Patentee's submissions

The allegation against the Opponent/ Patentee is that it is not working the patent to its "fullest extent that is reasonably practicable" as it is highly priced. In order to work the patent to its "fullest extent that is reasonably practicable", the opponent is prepared to modify the current PAP thereby reducing the price of the drug for those patients who cannot afford the original price to a level by which it has been proven by Cipla's sale figures (as mentioned in the affidavit dated February 8, 2012 of Dr. Manish Garg) to cover a very large number of patients.

It was submitted that Cipla being in the market has cut the opponent's market share thereby preventing them to work the invention to the fullest extent that is reasonably practicable.

Section 86 in fact gives preference and the first right option to the patentee to work the patent to the fullest extent that is reasonably

practicable before any CL is granted. For this purpose, the present CL proceedings may be adjourned for one year.

It was submitted that Section 86 of the Patents Act obliges the Learned Controller to first consider and give first option right to the inventor/patentee to work the patent to its fullest extent that is reasonably practicable. If the allegation is that the patent is not being fully worked because of the high price, it is in the interest of justice that an opportunity has to be given to the inventor/patentee to reduce the price below the "reasonably affordable price" to those who cannot afford the original price.

In so far as the compliance of conditions imposed by the Learned Controller for the adjournment is concerned, in the event of non-compliance, it is submitted that the Controller can simply grant the CL on the expiry of the adjournment period under Section 86 of the Patents Act.

Applicant's submissions:

The Patentee at the time of hearing made an oral request for adjournment of the hearing under Section 86 (of the Patents Act) by 12 months so as to enable the patentee to work the invention in India to the fullest extent. In addition, the Patentee came up with a proposal that they would provide the product to deserving patients at Rs 30,000 per month and sought adjournment on that basis. Such request being a mere demurrer, cannot be entertained at all even on merits because:

- Section 86 would require the Ld.Controller to first arrive at a finding, the "**time**" that has elapsed after sealing of the patent has been "*insufficient*" to enable the patentee to work the invention in India. Further, the power to adjourn is curtailed by Section 86(2) which clearly stipulates that the adjournment shall **not** be granted

for the asking, but only upon a clear satisfaction that the Patentee has taken with promptitude, steps to work the invention in India on a commercial scale to an adequate extent.

- A proper reading of section 86 would require *fulfillment* of following conditions before any adjournment is granted:
    - Application from the Patentee conceding that they have not been able to work the patented invention after its grant, and giving reasons why they could not do so from date of grant till date of CL application and steps that they plan to take to work the patented invention in future
    - On the basis of the above, the Ld. Controller could arrive at a finding and be "satisfied" that the invention though not worked till date, could be worked in future by the Patentee.
- In the case at hand no application from patentee- only oral plea: Patentee has made no serious plea for adjournment; no specific application was filed. Even in its oral arguments, the Patentee did not concede that they could not work the invention in a timely manner after its grant and no request for working has been made so far. The argument made is a mere request for adjournment without any assurance that the Patentee shall work the invention nor any details of the mode and manner of working the invention- no change in market price or assurance of greater availability of the drug in the market has been made. In the absence of such reasons, any adjournment is unwarranted and unsustainable.
- Patentee is guilty of absolute neglect and delay: Despite launching the product in the world market in 2006, the Patentee did not launch it in India until 2009- though the patent was granted in 2008

thus the patentee waited for 2 years and no logical reason for such delay has been ascribed till date- neither Patentee has conceded to the delay nor given reasons for the delay ; The key feature of Section 86 is the time factor and the satisfaction that time was insufficient- the satisfaction of the Ld Ld Controller can be gleaned only from reasons if any and ascribed by the Patentee. And, Section 86(2) specifically intends to curb such unexplained delay. In the teeth of such intendment of the legislation, and the unexplained delay and latches by the Patentee in working the patented invention, no adjournment is warranted and not reasonable.

- Bayer as a company with all its supply infrastructure existed as of 2005, as well as 2007 as well as 2011. It is pertinent to note that the demand for the drug always existed whether in 2007 or 2009 or 2011 and the Patentee has not explained why there was delay in working the patent. Thus, the basic requirement of Section 86 remains unfulfilled making out no case for adjournment at all.
- It is pertinent to note that the law makers while framing of Sec 84 of Patents Act had given the Patentee 3 years from the date of grant of Patent as a reasonable period for the Patentee to work the invention. Failure to do so invites consequences outlined in Chapter XVI, Section 84. In this case, even though the Patent was granted in 2008, Patentee not taken any effective steps all these four (4) years to see that the Patent is worked in India as in other countries; which amply demonstrates the neglect on part of the Patentee.
- Further the Patentee, though pleads for adjournment, does not plead that "time" has been insufficient to work the invention in India- rather the Patentee vehemently contests this fact and states

that they have worked the patent in India to an adequate extent : hence, even for this reason, the request for adjournment must be dismissed in limini.

- Section 84(6)(iv) precludes consideration of matters after the date of filing of the compulsory license application: Section 84(6)(iv) clearly states that "... *but shall not be required to take into account matters subsequent to the filing of the application*" meaning thereby that the Ld Controller is only required to consider the state of affairs that existed **on the date of filing of the Application for compulsory license** and not beyond; considering any proposal by the Patentee made at the time of hearing would be beyond the scope of Section 84(6)(iv);
- Even with the proposal, product price in Open market price remains unchanged and Section 84 is only concerned with market price: Patentee maintains that it shall continue to sell the patented invention at the rate Rs. 2,80,000/- in the open market (chemist shop) to the affordable patients and the reduced price is only for certain deserving patients- the scope of inquiry under section 84 and the present application centers around whether the product is available in the open market at reasonably affordable price, and not the merits of the patient assistance program of the patentee; hence the proposal is no proposal at all and there is nothing for consideration by the Ld Controller in this respect also;
- No rational classification: No logic or rationale including criteria has been defined by the Patentee as to how the "deserving class" would be carved out from the patient base;
- Ld Controller has no power to arbitrate, mediate or settle: Ld Controller has no power under section 86 or any other provision to

settle matters in lieu of grant of Compulsory license– such powers are bestowed on a civil court under Section 151 of the CPC;

- Ld Controller has no power to classify public: Ld Controller has no power under the Act to classify the public into deserving and non-deserving for any reason whatsoever; accepting the proposal would necessarily require the Ld Controller to make such classification which is beyond the jurisdiction of the Ld Controller;
- Ld Controller has no power to grant adjournment on the basis of proposal given by Patentee- such power can be exercised only on a finding of insufficient time: It is important to note that the Ld Controller has no power to take into Account any settlement proposals and grant adjournment on that basis. Ld Controller under the Act especially Section 86 is only empowered to arrive at a finding that *time* for working has been insufficient, and on that basis grant adjournment. Hence Patentee's proposal cannot form basis for adjournment;
- Ld Controller has no power to take into account subsequent events: It is pertinent to note that Sorafenib was launched in the world in 2006; Cipla entered the market around April-May 2010 and till date, the Patentee has not bothered to work the invention. However, now, upon filing of the Application for Compulsory license, the Patentee has expressed a desire to work the invention- the material date for adjudication under Section 84 is "the "*date of the compulsory license Application*"- same can be gleaned from Section 84(6)(iv)-"*..but shall not be required to take into account matters subsequent to the filing of the date of filing of the application*" ; Section 84(a)-"*... have not been satisfied*";
- Proposal is an attempt to remedy an irrational PAP program: Under the PAP program, the patient was required to pay Rs 2-5 lakhs

upfront regardless of whether he lived or not; same has been modified and now same amount is being collected in installments [Rs 2,80,000/9= 30,000].

Decision

Section 86 of the Patents Act, 1970, under which the adjournment has been sought by the Patentee is as follows:

"86. Power of Controller to adjourn applications for compulsory licenses, etc., in certain cases.

(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve months in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of

adjournment ordered under this sub-section shall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent."

The Applicant's contention that only an oral submission was made is misplaced. The Patentee has given the request in writing supported by an affidavit on the issue of modified Patient Assistance Program (PAP).

The Patentee's main contention is that due to the presence of Cipla in the market, the Patentee could not work the invention to the fullest extent that is reasonably practicable as Cipla undercut them. It is pertinent to mention that the drug was developed and marketed globally right from the year 2006, i.e. two years prior to the grant of patent in India. The present proposal of the patentee is that they are willing to offer the drug at a price of Rs. 30,000 through their PAP program. As per their own submission, the Patentee has two schemes under its PAP program. Under the first scheme termed as 1+6, the patient has to pay for one month stock of the drug and will get the supply for six months free. Under the second scheme termed as 2+10, the patient has to pay for two months stock of the drug and will get the supply for ten months free. The Patentee has proposed that they will supply the drug to needy patients based on the recommendation of the Oncologist that the patients is needy and has no means to pay.

The Patentee launched the product in other countries in 2006, as is evident from their sales provided by the Applicant, which have not been controverted by the Patentee. The Patentee got the License for importing and marketing the drug in India on 01.08.2007. The Patentee got another License from the Directorate General of Health Services to import and market the drug on 22.01.2008. Assuming that the actual permission to import and market the drug was given on 22.01.2008, the Patentee's conduct of not importing the drug till 2008 and importing in small quantities in 2009 and 2010, is beyond explanation. The Patentee has alleged that Cipla did not allow the sales to flourish. However, it is pertinent to mention that M/s.Cipla entered the market only in April-May 2010 and the Patentee had approximately 2 years after that to suitably modify its pricing strategy so as to work the invention on a commercial scale to an adequate extent. The Patentee thus took no adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

The Patentee argued that "treating unequal as equal" is discriminatory and is not permissible under law. Placing "the rich class" and "the lower class" in one category at the expense of the patentee is unreasonable and cannot be the intention of the legislature. The Patentee was not estopped in any manner from treated equals as equals and unequals as unequals. The Patentee had four years from the date of grant to apply differential pricing for different sections of the public in India.

In my view the two essential conditions for invocation of Section 86 of the Act are as follows:

(1) the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the

invention to be so worked to the fullest extent that is reasonably practicable; **and**

(2) the patentee has taken with promptitude adequate or reasonable **steps** to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

As discussed in 9 above, the Patentee did not import the drug at all in 2008, and imported in small quantities in 2009 and 2010. In the facts and circumstances of this case, I do not believe that the time which has elapsed since the grant of the patent has been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable. Further, I do not also see any prompt action on the part of the Patentee to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

Another reason for non-invocation of this provision is the Section 84(6), which states as follows:

"(6) In considering the application filed under this section, the Controller shall take into account,—

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

... ...

but shall not be required to take into account matters subsequent to the making of the application."

This provision specifically bars the Controller from considering any measures taken by the Patentee subsequent to the making of the Application. The intention of the Legislature appears to be that subsequent measures by the Patentee to frustrate the proceedings shall

not be considered. In my view, the present proposal falls within the four corners of this prohibition.

The proposal of the Patentee appears to be philanthropic in nature, as per the submission of the Patentee. In the present proceedings, we are not concerned with philanthropy, which no doubt is appreciable. Such actions cannot be construed as steps to work the invention on a commercial scale to an adequate extent. The request of the Patentee for adjournment is therefore rejected.

14. **Terms and conditions**

Having decided to grant the Compulsory License under Section 84 of the Act, I now proceed to settle the terms and conditions of the License in the light of the provisions contained in Section 90 of the Act.

Applicant's submissions

Following terms and conditions are acceptable to the Applicant:

i. Right to manufacture and sell Sorafenib shall be limited to the Territory of India.

ii. The products under license shall be manufactured only to cover the patients who are afflicted by renal and hepatic carcinoma.

iii. Royalty shall be paid to the Patentee at the rate as fixed by the Controller of Patents.

iv. Initially, a price of Rs. 74/- per tablet is proposed, which works out to be Rs.8,800/- per month for therapy.

v. The Applicant also commits to give the product free of cost to atleast 600 needy and deserving patients per year.

The Applicant has also submitted the cost break-up as follows:

Particulars	Amount (Rs.)
M.R.P. (inclusive of sales tax)	8900
Margin to distributor, stockiest and retailer (approximately 30% on M.R.P.)	2670
Cost of manufacture of the product SORAFENAT	4856
Billing price of company to distributors	6105
Margin to the company	1250

The Applicant also submitted that royalty shall be paid from the margin to the Applicant.

Patentee's submissions

The Patentee has submitted the following terms and conditions:

i. Non-exclusive license to make sorafenib tosylate (API of Nexavar), to formulate into tablet form, to sell for the purpose of treating HCC and RCC in humans; all rights non-transferable and limited to the Applicant only (no right to sublicense, assign, or delegate to others) and to India only (no right to import or export);

ii. License does not include any right to represent publicly or privately that the Applicant's product is the same as the Patentee's or that the Patentee is in any way associated with the Applicant's product. The Applicant's product must be visibly distinct from the Patentee's product (e.g. in color

and / or shape); the name must be distinct, and the packaging must be distinct. The Patentee expressly does not grant any copyright or trademark rights with he license and will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind.

iii. Raising the prices, failing in market in all states in India, and failing to provide free drug to indigent persons shall each be considered a material breach;

iv. The Applicant is solely and exclusively responsible for its product and for all associated product liability, and will indemnify the Patentee, its Directors, Officers, Employees, Agents, and affiliates against any and all damages arising from or associated with the Applicant's activities. The Applicant will carry insurance in an amount sufficient to cover such damages ($10 million) and upon request will provide certificates evidencing such coverage;

v. Royalty – 15% of net sales, payable in US dollars. There are no milestones or guaranteed minimums but there are also no credits or deductions for any other fees or royalties paid to any third parties;

vi. Term is until first to occur of: a) decision by the relevant government authority that the conditions for granting compulsory license no longer exist, or b) expiration of Indian Patent 215758. This agreement will be terminated upon a) the Applicant's breach of any term, representation, or warranty if such breach is not cured within 30 days; or b) upon bankruptcy of the Applicant.

vii. There are no additional implied licenses to any other patents owned by the Patentee now or in future. There are no representations or warranties of validity or enforceability. The Patentee is not obligated to enforce against infringement by third parties;

viii. The Applicant not to challenge the validity of Indian Patent 215758 in any way, directly or indirectly;

ix. The Patentee is free to do whatever it wishes with its residual patent rights subject to the non-exclusive license to the Applicant, and is free to compete with the Applicant and to grant licenses to third parties to compete with the Applicant; and

x. The license will include such other terms as are normal in the Industry (e.g. record keeping, reporting, mechanisms for conversion from rupees to dollars, details of indemnification etc.)

Decision

Royalty

Article 31 (h) of TRIPS Agreement states as follows:

"(h) the right holder shall be paid adequate remuneration in the circumstances taking into account the economic value of the authorization;...."

The unamended Patents Act, 1970 provided for a ceiling of 4 percent royalty to be paid to the patentee in case of a compulsory license. However, this ceiling was removed by the Patents (Amendment) Act, 2002 and it was left to the Controller to decide on a case to case basis as to quantum of royalty or other remuneration to be paid to the patentee by the compulsory license holder.

Section 90(1) of the Act states as follows:

"90. Terms and conditions of compulsory licences. –

(1) In settling the terms and conditions of a license under section 84, the Controller shall endeavour to secure—

> *(i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;……"*

During the course of hearings, the Patentee submitted that the cost of making the invention and developing a new medical entity (NME), like the drug in this case, works out to be about 1.8bn€. However, the figure arrived was for the cost of R&D for five years preceding 2010. In the absence of any definite figure on the cost of developing and making it available in the market, including the cost of patenting and maintaining the patent made available to me, I am unable to arrive at the actual cost involved in making this particular invention and developing the same. However, I am inclined to believe that the Patentee has spent considerable sum of money for purpose of making and developing this invention.

I am obligated to consider the nature of this particular invention especially with regard to the possible number of consumers, who require the drug in this case in order to arrive at a reasonable royalty to the Patentee. Going by the GLOBOCAN 2008, I find that the number of patients requiring this drug in India is not very high when compared to other recently patented drugs like HIV drugs.

I have also carefully analysed the royalty practices / guidelines generally adopted globally. United Nations Development Program (UNDP) specifically recommended that rates normally be set at 4% and adjusted upwards as much as 2% for products of particular therapeutic value or reduced as much as 2% when the development of the product has been partly supported with public funds, i.e. for a range of 2 to 6%. In the present case, I am satisfied that anything lesser than 6% would not be just and reasonable given the facts and circumstances of this case as discussed above. Hence, I hereby settle that the royalty be paid to the patentee in this compulsory as 6% of the net sales of the drug by the Licensee. I have also considered the other terms and conditions agreed by the Applicant and sought by the Patentee.

15. **ORDER**

I hereby grant a compulsory license (hereinafter referred to as 'license') under Section 84 of the Patents Act, 1970 to M/s. Natco Pharma Ltd, Natco House, Road No. 2, Banjara Hills, Hyderabad-500033, Andhra Pradesh, India (hereinafter referred to as 'licensee') in patent number 215758 (hereinafter referred to as 'patent') granted to M/s. Bayer Corporation, 100 Bayer Road, Pittsburg, PA 15205-9741, USA (hereinafter referred to as 'licensor') with the following terms and conditions:

a. The price of the drug covered by the Patent, sold by the licensee shall not exceed Rs.8880 for a pack of 120 tablets, required for one month's treatment.
b. The licensee shall maintain accounts of sale etc. in a proper manner and shall report the details of sales to the Controller as well as the

Licensor on a quarterly basis, on or before fifteenth day of the succeeding month.

c. The licensee shall have the right to manufacture the drug covered by the Patent only at his own manufacturing facility and shall not in any whatsoever outsource the production.

d. The license is non-exclusive.

e. The license is non-assignable.

f. The licensee shall pay royalty at the rate of 6% of the net sales of the drug on a quarterly basis and such payment shall be affected on or before fifteenth day of the succeeding month.

g. The license is granted solely for the purpose of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the Territory of India.

h. The licensee shall supply the drug covered by the Patent to atleast 600 needy and deserving patients per year free of cost. The licensee shall annually submit in the form of an affidavit the details of such patients, i.e. name, address and the name of the treating oncologist, to the Office of the Controller of Patents and such report shall be submitted on or before 31st January of the year, in respect of the preceding year.

i. The licensee shall not have the right to import the drug covered by the Patent.

j. The license is for the balance term of the patent.

k. The license does not include any right to represent publicly or privately that the Licensee's product is the same as the Licensor's or that the Licensor is in any way associated with the Licensee's product. The Licensee's product must be visibly distinct from the Licensor's product (e.g. in color and / or shape); the trade name

must be distinct, and the packaging must be distinct. The Licensor will provide no legal, regulatory, medical, technical, manufacturing, sales, marketing, or any other support of any kind to the Licensee.

l. The Licensee is solely and exclusively responsible for its product and for all associated product liability. The Licensor, its Directors, Officers, Employees, Agents, and affiliates shall not be held liable in any manner whatsoever for any action of the licensee.

m. The Licensor is free to do whatever it wishes with its residual patent rights subject to the non-exclusive license to the Licensee, and is free to compete with the Licensee and to grant licenses to third parties to compete with the Licensee.

Given under my hand my seal on this the 9th day of March 2012.

(P. H. Kurian)
Controller of Patents

Ecuador

IEPI

INSTITUTO ECUATORIANO DE LA PROPIEDAD INTELECTUAL IEPI
DIRECCIÓN NACIONAL DE PROPIEDAD INDUSTRIAL

TRAMITE No.: 000006 (Licencia Obligatoria para Fármaco)
SOLICITANTE: ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A.

PATENTE No.: PI-08-1913
DENOMINACION: "UNA NUEVA SAL"
TITULAR: GLAXO GROUP LIMITED
RESOLUCION No.:

INSTITUTO ECUATORIANO DE LA PROPIEDAD INTELECTUAL IEPI.- Dirección Nacional de Propiedad Industrial.-

Quito, a 12 de noviembre del 2012; las 09h35

ANTECEDENTES:

El 15 de junio del 2012, ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. solicitó la emisión de una licencia obligatoria para uso público no comercial del principio activo LAMIVUDINA + ABACAVIR protegido bajo la patente No. SP-98-2505, solicitada el 14 de mayo de 1998, concedida el 05 de enero del 2007, mediante titulo No. PI-08-1913, vigente hasta el 14 de mayo del 2018.

Mediante escrito de 15 de junio de 2012, María José Zurita en su calidad de procuradora judicial y apoderada general de la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. manifiesta que " la combinación LAMIVUDINA + ABACAVIR se encuentra actualmente patentado, bajo el No. De Patente SP 98-2505, concedida el 5 de enero del 2007, cuyo titulo es PI 08-1913, vigente hasta el 14 de mayo de 2018, perteneciente a la compañía GLAXO GROUP LIMITED, representada por su apoderado el Dr. Enrique Chiriboga " Señala también que "Esta combinación antirretroviral, destinada a los medicamentos que son inhibidores de la Francriptase inversa análoga de los nucleosidos, cuya acción farmacológica es el tratamiento de la enfermedad VIH/SIDA, es necesario para la fabricación de medicamentos requeridos para el tratamiento de pacientes con la enfermedad anteriormente indicada. El Ecuador en su afán de combatir esta enfermedad, incluso expidió la Ley 2000-11 de Prevención y Asistencia Integral del VIH/SIDA, promulgada en el Registro Oficial 58 del 14 de abril del 2000, así mismo en el art. 56 de la decisión 486 de la Comunidad Andina de Naciones, a la cual pertenece el Ecuador, establece 'previa declaratoria de un país miembro de la existencia de razones de interés público o de emergencia, o de seguridad nacional y sólo mientras estas razones permanezcan, en cualquier momento se podrá someter la patente a Licencia Obligatoria.'

Así mismo, mediante decreto No. 118, publicado en el registro Oficial No. 67, del 16 de noviembre del 2009, el Presidente Constitucional de la República, declaró de interés público el acceso a las medicinas utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana, por lo que se podrá conceder licencias obligatorias sobre las patentes de medicamentos de uso humano."

A través de providencia de 22 de junio de 2012, notificada el 25 de los mismos mes y año, se acepta a trámite la solicitud de licencia obligatoria para uso público no comercial del fármaco presentada por ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A., además se dispone se notifique a GLAXO GROUP LIMITED, en calidad de titular de la patente de invención, objeto de la presente licencia obligatoria, con el contenido de la solicitud de licencia obligatoria para uso público no comercial y demás documentos ingresados, de conformidad con lo dispuesto por el artículo 7 de la Resolución No. 10-04 P.II.PI de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010 que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos"*, y se dispone se oficie al Ministerio de Salud Pública a fin de que emita el informe correspondiente, respecto de si el principio activo denominado LAMIVUDINA + ABACAVIR, objeto de la presente solicitud, es una medicina de uso humano de las utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sea prioritaria para la salud pública, según lo dispuesto por el artículo 8 del citado instructivo.

Con oficio N. 014-2012 DNPI-IEPI dirigido a la señora Magister Carina Vance Mafla, Ministra de Salud Pública, se le solicita que de conformidad con lo establecido en el artículo 2 del Decreto Ejecutivo 118 de 23 de octubre de 2009 y el artículo 8 de la Resolución No. 10-04 P-IEPI de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010, que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos"*, se sirva informar a ésta Dirección Nacional de Propiedad Industrial del Instituto Ecuatoriano de la Propiedad Intelectual, si los principios activos LAMIVUDINA + ABACAVIR, son principios activos para la fabricación de medicamentos utilizados para el tratamiento de enfermedades que afecten a la población ecuatoriana, y si son considerados prioritarios para la salud pública.

El 18 de julio de 2012, Sebastián Donoso Bustamante, a nombre y en representación de Bustamante & Bustamante, que a su vez es mandataria de GLAXO GROUP LIMITED solicitó la apertura de la causa a prueba.

Mediante providencia de 19 de julio de 2012, notificada el 25 de los mismos mes y año, se agregó al expediente el escrito presentado por GLAXO GROUP LIMITED y en virtud de las garantías básicas del debido proceso y el derecho a la defensa consagrados en el literal h) del numeral 7 del Art. 76 y el derecho de petición numeral 23 del Art. 66, de la Constitución de la República del Ecuador; y de conformidad con lo dispuesto en el número 4 del Art. 147 del Estatuto del Régimen Jurídico Administrativo de la Función Ejecutiva, por así haberlo solicitado de forma expresa el titular de la patente, se dispuso la apertura del periodo de prueba.

Con oficio No. MSP-SDM-10-2012-0935-O de 03 de agosto de 2012 remitido por el Dr. Hugo Miguel Malo Serrano, Ministro de Salud Pública Subrogante, dirigido al Dr. Andrés Ycaza, en su calidad de Presidente del Instituto Ecuatoriano de la Propiedad Intelectual, se indica que el medicamento LAMIVUDINA + ABACAVIR es un antirretroviral utilizado para el tratamiento de la infección por el VIH; mediante Oficio No. IEPI-PRES-IEPI-2012-0112-O de 03 de agosto del 2012, dirigido al Dr. Hugo Miguel Malo Serrano en su calidad de Ministro de Salud Pública Subrogante, el Dr. Andrés Ycaza, Presidente del Instituto Ecuatoriano de la Propiedad Intelectual, solicita una aclaración de si el principio activo LAMIVUDINA-ABACAVIR es empleado para el tratamiento de enfermedades que afecten a la población ecuatoriana y si es considerado prioritario para la salud pública.

Mediante oficio No. MSP-SDM-10-2012-1039-O de 20 de agosto de 2012, remitido por el Dr. Hugo Miguel Malo Serrano en su calidad de Ministro de Salud Pública Subrogante, al Dr. Andrés Ycaza, en su calidad de Presidente del Instituto Ecuatoriano de la Propiedad Intelectual, aclara que el principio activo LAMIVUDINA-ABACAVIR es empleado para el tratamiento de enfermedades que afecten a la población ecuatoriana y es prioritario para la salud pública.

El 23 de agosto de 2012, Roque Bernardo Bustamante, en su calidad de representante de la apoderada de GLAXO GROUP LIMITED, presenta escrito de prueba, del mismo modo el 29 de agosto de 2012 la Ab. María José Zurita Luna en su calidad de Procuradora Judicial y Apoderada General de la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. presenta escrito de prueba.

A través de providencia de 26 de octubre de 2012, se agregan al expediente los Oficios Nos. MSP-SDM-10-2012-0935-O de 03 de agosto de 2012, IEPI-PRES-IEPI-2012-0112-O de 03 de agosto de 2012, MSP-SDM-10-2012-1039-O. Además se agregan al expediente y se proveen los escritos de prueba presentados por: a) GLAXO GROUP LIMITED el 23 de agosto de 2012; y b) ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. el 29 de agosto de 2012.

El 25 de septiembre de 2012, la Ab. María José Zurita Luna en su calidad de Procuradora Judicial y Apoderada General de la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. presenta un escrito en el que señala que por un error tipográfico se señaló en la solicitud de licencia obligatoria para uso público no comercial del principio activo LAMIVUDINA + ABACAVIR, que la licencia solicitada sería utilizada para producción, cuando debería ser producción e importación.

A través de providencia de 01 de noviembre del 2012, notificada el 06 del mismo mes y año se agrega al expediente, con notificación contraria, el escrito presentado el 25 de septiembre de 2012, y se considera la aclaración realizada.

PARA RESOLVER SE CONSIDERA:

PRIMERO.- Que el artículo 32 de la Constitución de la República del Ecuador establece que, la salud es un derecho que garantiza el Estado, cuya realización se vincula al ejercicio de otros derechos que sustentan el buen vivir.

Que el buen vivir o Sumak Káusay, se basa en construir de forma democrática y paulatina las condiciones materiales y espirituales de la colectividad, bajo parámetros de entendimiento, identidad cultural, armonía social, ambiental, solidaridad y respeto a la Salud y a la Vida de ahí que, el régimen de desarrollo que consta en la Constitución nacional pretende alcanzar el Buen Vivir.

SEGUNDO.- Que el artículo 3.1 de la Constitución de la República señala que el debe primordial del Estado **el garantizar** sin discriminación alguna el efectivo goce de lo derechos **en la Constitución** y en los Instrumentos internacionales, e **constitucionalmente** reconocidos como es el derecho a la salud

TERCERO.- Que el artículo 363 numeral 7 de la Constitución de la República señala que, dentro de los deberes del régimen del buen vivir es obligación del Estado en materia de salud: "Garantizar la disponibilidad y acceso a medicamentos de calidad, seguros y eficaces, regular su comercialización y promover la producción nacional y la utilización de la biodiversidad existente, priorizando aquellos que respondan a las necesidades epidemiológicas de la población, así como el acceso a medicamentos, los intereses de la salud pública prevalecerán sobre los económicos y comerciales".

CUARTO.- Que el artículo 25 de la Declaración Universal de Derechos Humanos señala entre otros aspectos que toda persona tiene derecho a un nivel de vida adecuado que le asegure, así como a su familia, la salud y el bienestar.

QUINTO.- Que el Ecuador es miembro de la OMC desde el 21 de enero de 1996 y en consecuencia suscribió el artículo 31 de las normas sobre Aspectos Relacionados al Comercio de la Propiedad Intelectual (ADPIC) de la Organización Mundial de Comercio, mediante el cual se reconoce a los países la emisión licencias obligatorias para patentes de medicamentos que sirvan para combatir y mitigar enfermedades de interés público.

SEXTO.- En la Declaración Ministerial principal de Doha sobre acuerdos de ADPIC y Salud Pública adoptada el 14 de noviembre de 2001, los gobiernos de los miembros de la OMC, dejan establecido el que cada Estado miembro tenga "el derecho a conceder licencias obligatorias y el derecho de determinar las bases sobre las cuales se conceden tales licencias". Agregan que la mencionada Declaración puntualiza que el Acuerdo de ADPIC debería ser interpretado y aplicado para "promover el acceso de medicamentos para todos".

SÉPTIMO.- Que de conformidad con lo señalado en el artículo 2 del Decreto Ejecutivo No. 118 de 16 de noviembre de 2009, en concordancia con los Arts. 61 de la Decisión 486 de la Comisión de la Comunidad Andina y 154 de la Ley de Propiedad Intelectual, la Dirección Nacional de Propiedad Industrial previa declaratoria del Presidente de la República acerca de la existencia de razones de interés público de emergencia o de seguridad nacional, podrá someter la patente a licencia obligatoria en cualquier momento.

OCTAVO.- Que en el artículo 1 del Decreto Ejecutivo No. 118 de 16 de noviembre de 2009 se dispone "Declarar de interés público el acceso a las medicinas utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sean prioritarias para la salud pública, para lo cual se podrá conceder licencias obligatorias sobre las patentes de los medicamentos de uso humano que sean necesarios para sus tratamientos".

NOVENO.- Que ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. solicitó la emisión de una licencia obligatoria de importación y producción para uso público no comercial del principio activo LAMIVUDINA + ABACAVIR, protegido bajo la patente No. SP-08-2005, solicitada el 14 de mayo de 1998, concedida el 05 de enero del 2007, mediante título No. PI-08-1913, vigente hasta el 14 de mayo del 2018.

DÉCIMO.- Que el artículo 8 de la Resolución No. 10-04 P-IEPI de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010 que contiene el "Instructivo para la concesión de licencias obligatorias de patentes de fármacos" expresamente dispone que "Una vez revisada la documentación y notificado el titular de la patente, el IEPI, a través de

la DNPI solicitará al Ministerio de Salud Pública que informe si la materia objeto de la solicitud es una medicina de uso humano de las utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sean prioritarias para la salud pública."

Situación que efectivamente se llevó a cabo mediante oficio No. MSP-SDM-10-2012-0935-O de 03 de agosto de 2012 remitido por el Dr. Hugo Miguel Malo Serrano, Ministro de Salud Publica Subrogante, dirigido al Dr. Andrés Ycaza, en su calidad de Presidente del Instituto Ecuatoriano de la Propiedad Intelectual, donde se indica que el medicamento LAMIVUDINA + ABACAVIR es un antiretroviral utilizado para el tratamiento de la infección por el VIH, y mediante oficio No. MSP-SDM-10-2012-[illegible] de 2 de agosto de 2012 remitido por el Dr. Hugo Miguel Malo Serrano en su calidad de Ministro de Salud Publica Subrogante, al Dr. Andrés Ycaza en su calidad de Presidente del Instituto Ecuatoriano de la Propiedad Intelectual, en el que se indica que el medicamento LAMIVUDINA + ABACAVIR es empleado para el tratamiento de enfermedades que afectan a la población ecuatoriana y es prioritario para la salud pública.

Que la norma nada dice sobre probar la falta de acceso al medicamento o la falta de iniciativas para apoyar a las comunidades afectadas. En consecuencia ACROMAX LABORATORIO QUIMICO FARMACEUTICO no está en la obligación de hacerlo.

DECIMO PRIMERO.- En relación con lo antes expuesto también hay que señalar que no existe obligación normativa alguna que obligue al solicitante a probar la falta de acceso al medicamento, así como tampoco la falta de iniciativas para apoyar a las comunidades afectadas, no obstante debe acreditar que el medicamento cuya licencia se solicita va a ser utilizado para el abastecimiento del mercado interno y que será destinado al uso público comercial, cuestión que efectivamente se realizó a través de la solicitud de licencia obligatoria **para uso publico no comercial** presentada el 15 de junio de 2012 por ACROMAX LABORATORIO QUIMICO FARMACEUTICO y en el escrito de la misma fecha también presentado por ACROMAX LABORATORIO QUIMICO FARMACEUTICO.

DECIMO SEGUNDO.- Que si bien GLAXO GROUP LIMITED considera y supone que "ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. ha solicitado equivoca e infundadamente una licencia obligatoria pues aparentemente no persigue el USO PUBLICO NO COMERCIAL" dentro de un trámite administrativo el análisis de la autoridad no debe sustentarse en consideraciones o supuestos alegados y no probados por las partes, por el contrario debe sustentarse en las pruebas escritas y demás documentación aportada, al respecto el articulo 9 de la Resolución No. 10.04.R.C.I.P. de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010 que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de farmacos"* señala que la DNPI resolverá el caso **analizando la solicitud**, el informe del Ministerio de Salud Publica y la documentación adjunta.

En consecuencia, conforme **se desprende de los** documentos detallados en el considerando anterior **queda clara y debidamente acreditada** la calidad de uso publico no comercial de la licencia **obligatoria solicitada**, contrario a lo que GLAXO GROUP LIMITED considera y supone.

DECIMO TERCERO.- Que para determinar la existencia de una emergencia nacional se **deben considerar una serie de circunstancias y factores**, y no solamente un dato,

estadístico extranjero que no es vinculante y en el mejor de los casos puede ser considerado meramente referencial y de ser el caso sujeto a verificación.

DECIMO CUARTO.- Que como bien señala GLAXO GROUP LIMITED en su escrito de 2[illegible] de agosto de 2012, la Declaración relativa al Acuerdo sobre los ADPIC y la Salud Pública en su artículo 31 literal b) señala que: "Sólo podrán permitirse esos usos cuando antes de hacerlos, el potencial usuario haya intentado obtener la autorización del titular de los derechos en términos y condiciones comerciables razonables y esos intentos no hayan surtido efecto en un plazo prudencial. Los Miembros podrán eximir de esta obligación en caso de emergencia nacional o en otras circunstancias de extrema urgencia..."

Sin embargo GLAXO GROUP LIMITED omite mencionar que la norma también prevé que los miembros podrán eximir de esta obligación a los casos de uso público no comercial, contraviniendo de esta manera un principio moral y de buena práctica profesional contenido en el artículo 4 del Código de Ética Profesional Avellan Ferres, que expresamente dispone: "El abogado no podrá aconsejar actos dolosos, afirmar o negar con falsedad, **hacer citas inexactas, incompletas** ni realizar acto alguno que estorbe la buena administración de justicia." (Énfasis agregado).

DECIMO QUINTO.- En consecuencia en el presente caso se puede eximir de la obligación prevista en el artículo 31 literal b) del Acuerdo sobre los ADPIC, toda vez que se trata de una licencia obligatoria de uso público no comercial. En este sentido también hay que señalar que la declaración de Doha sobre los acuerdos ADPIC y la Salud Pública señala que cada Estado miembro "tiene el derecho de conceder licencias obligatorias y la libertad de determinar las bases sobre las cuales se conceden tales licencias". Además puntualiza que el ADPIC debe ser interpretado y aplicado de tal modo que asegure "promover el acceso a los medicamentos para todos", del mismo modo la estrategia mundial sobre "salud pública, innovación y propiedad Intelectual" de la Asamblea Mundial de Salud, AMS 61.21, párrafo 20 señala que "los derechos de Propiedad Intelectual no impiden ni deberán impedir que los Estados Miembros adopten medidas para proteger la salud pública."

DECIMO SEXTO.- Que el hecho de que GLAXO GROUP LIMITED a través de su subsidiaria GLAXOSMITHKLINE ECUADOR S.A. se encuentre proveyendo el medicamento en el mercado nacional, no prohíbe la expedición de una licencia obligatoria más aún cuando de forma expresa el artículo 11 de la Resolución No. 10-04 P-IEPI de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010 que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos"* en concordancia con el inciso tercero del artículo 154 de la Ley de Propiedad Intelectual y el literal a) del artículo 68 de la Decisión 486 de la Comisión de la Comunidad Andina reconoce que ella "no tendrá carácter exclusivo..." ni tampoco "menoscabará el derecho del titular de seguir explotando la patente."

DECIMO SEPTIMO.- Que el artículo 9 de la Resolución No. 10-04 P-IEPI de 15 de enero de 2010, publicado en el RO No. 141 de 2 de marzo de 2010 que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos"* en concordancia con el inciso **segundo del artículo 154 de la Ley de Propiedad Intelectual y el inciso segundo del artículo 62 de la Decisión 486 de la Comisión de la Comunidad Andina** prescribe que:

"Cumplidos los pasos anteriores, la DNPI analizará la solicitud, el informe del Ministerio de Salud Pública y la documentación adjunta y resolverá motivadamente el caso, concediendo o denegando la licencia obligatoria solicitada, en función de sus circunstancias propias.

En caso de que la resolución conceda la licencia obligatoria, en el mismo acto administrativo se deberá establecer el alcance, objeto y plazo por el cual se la concede, así como el monto y condiciones de pago de las regalías de dicha licencia y demás condiciones establecidas en la normativa aplicable."

DECIMO OCTAVO.- Que los artículos 65 y 68 literal d) de la Decisión 486 de la Comisión de la Comunidad Andina, prescriben:

"Art. 65.- Previa declaratoria de un País Miembro de la existencia de razones de interés público, de emergencia o de seguridad nacional y ***sólo mientras estas razones permanezcan se podrá someter la patente a licencia obligatoria****. En tal caso, la oficina nacional competente otorgará las licencias que se le soliciten. El titular de la patente objeto de la licencia será notificado cuando razonablemente sea posible..." (Énfasis agregado)*

"Art. 68.- En adición de lo establecido en los artículos precedentes, las licencias obligatorias están sujetas a lo siguiente:

d) El alcance y la duración se limitarán en función de los fines para los que se concedieran;"

En consecuencia, el alcance y tiempo de duración de la licencia obligatoria se limita al cumplimiento de los fines para los que se concedió lo que se podrá valorar objetivamente en la medida en que permanezcan, o no, las razones de interés público, emergencia o seguridad nacional que motivaron la expedición de la licencia obligatoria, o en su defecto hasta la fecha de vencimiento del derecho de exclusiva conferido mediante la patente.

DECIMO NOVENO.- Que respecto del monto y de las condiciones de compensación económica hay que señalar que de conformidad con el artículo 10 que contiene el *"Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos"*:

"Art. 10.- Se entiende por compensación económica, al pago de una remuneración adecuada que el solicitante de la licencia obligatoria reconocerá al titular de la patente, según las circunstancias propias de cada caso, habida cuenta del valor económico de la autorización."

En este sentido, y de conformidad con lo prescrito en el inciso 2do del artículo 62 de la Decisión 486 de la Comisión de la Comunidad Andina, el inciso segundo del artículo 154 y el literal d) del artículo 156 de la Ley de Propiedad Intelectual, la compensación debe ser fijada observando las circunstancias propias del caso concreto y considerando el valor económico de la autorización.

VIGESIMO.- Que el artículo 65 de la Decisión 486, en concordancia con el Decreto Ejecutivo No. 118 en su artículo número 4, señalan que es la autoridad competente, es decir, el Instituto Ecuatoriano de la Propiedad Intelectual – IEPI, a través de la Dirección

Nacional de Propiedad Industrial, el competente para fijar el monto y las condiciones de la compensación económica de la licencia obligatoria; por lo que corresponde a esta autoridad establecer su cuantía

Además, cabe indicar que esta facultad proviene de la necesidad de que no existan obstáculos innecesarios para la aplicación inmediata de los beneficios que genera la Licencia Obligatoria para el interés público ecuatoriano.

Del mismo modo a través del literal h) del artículo 31 del Acuerdo sobre los ADPIC, se exige que el titular de los derechos reciba "una remuneración adecuada según las circunstancias propias de cada caso, habida cuenta del valor económico de la autorización" Para el tema puntual sobre Licencias Obligatorias, la interpretación del Acuerdo sobre los ADPIC así como lo determinado en la Decisión 486 y el Decreto Ejecutivo 118, permiten que la autoridad señale los parámetros para el pago de la compensación económica en prestación de la utilización de la patente, para lo cual esta Dirección, toma en consideración los siguientes parámetros:

La publicación Guía Mundial sobre tarifa de regalías en farmacéuticos, es la publicación conjunta del programa de Desarrollo de las Naciones Unidas y la Organización Mundial de Salud, "pautas para remunerar el uso obligatorio de patentes de tecnologías médicas".[1] Como referencia se establece ejemplos de experiencias sobre las regalías determinadas por las autoridades en varios países, y se recomienda un método a gradas de regalías ("Tierde Royalty Method" or TRM), tomando en cuenta las tarifas y prácticas comunes mundialmente de las regalías para farmacéuticos. En consecuencia, con este método:

> Las regalías son independientes del costo de manufactura y varían directamente de los substitutos de valor terapéutico (El precio de alto ingreso) y la capacidad de pagar. El TRM provee un marco más racional de compartir los costos de investigación y desarrollo y puede ser más sustentable para algunos países de ingresos mediano o alto que son sensibles a las normas globales relacionadas con el compartir de los costos de investigación y desarrollo. El TRM provee regalías mucho más altas para países de ingreso mediano y alto con cargas bajas de la enfermedad y las regalías más bajas para los países que tienen los ingresos más bajos y las tasas más altas de la carga de la enfermedad.[2]

Esta Dirección establece el TRM como modelo para guiar el cálculo de regalías, consciente de la necesidad de contribuir e invertir en la investigación y desarrollo de nuevos medicamentos mundialmente.

Teniendo en cuenta que la salud es un derecho fundamental y prioritario y que de acuerdo con la decisión de la OMC de 30 de agosto de 2003, esta dirección toma en cuenta todos los aspectos previamente mencionados, en especial los índices de desarrollo humano proporcionado por las naciones unidas para el desarrollo en aras de brindar un trato igualitario para licenciante y licenciatario

VIGESIMO PRIMERO.- Que teniendo en cuenta lo anteriormente señalado se concluye que la presente **licencia obligatoria busca recaer** sobre una medicina de uso humano de

[1] WHO TCM 2005.1, "Remuneración guidelines for none voluntary us of patente on medical technologies", Health Economics and Drugs, TCM Serie No. 13, OMS/PNUD, escrito por James Love
[2] Ibid. página 85.

las utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sean prioritarias para la salud pública y cumple con todos los requisitos previstos en la normativa vigente.

Por lo expuesto, esta Dirección Nacional en ejercicio de sus facultades,

RESUELVE: 1.- Conceder la solicitud de licencia obligatoria de importación y producción para uso publico no comercial sobre la patente de invención contenida en el trámite No SP-98-2505 con No. de título PI-08-1913 denominada "Una nueva sal", cuyo titular es GLAXO GROUP LIMITED, la cual contiene el principio activo denominado LAMIVUDINA + ABACAVIR, a favor de la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A., la misma que será usada para su fabricación, oferta en venta, venta o uso del producto, importación para uso de estos fines y destinada al Uso Público No Comercial.

2.- Otorgar como periodo de vigencia de la licencia obligatoria, el plazo que le reste de vigencia a la patente concedida en el trámite No. SP-98-2505, mediante título No. SP-98-2505, denominada "Una nueva sal", cuyo titular es GLAXO GROUP LIMITED, esto es hasta el 14 de mayo del 2018.

3.- Ordenar a la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A el pago de la compensación económica siguiendo el cálculo del TRM.

Factor	Cálculo en USD ($)
Precio EEUU por frasco que contiene 30 unidades, precio obtenido en:	745
http://www.pharmacychecker.com/online-pharmacy-Epzicom-prices-cost.44768	
http://www.pharmacychecker.com/compare-drug-prices-online-pharmacies/Epzicom-600+300mg.44768.154109	
http://www.pharmacychecker.com/compare-drug-prices-online-pharmacies/Epzicom-600&252;–mg.44768.144578	
http://www.pharmacychecker.com/compare-drug-prices-online-pharmacies/Epzicom-600&252;–mg&282mg.44768.184330	
http://www.pharmacychecker.com/compare-drug-prices-online-pharmacies/Epzicom-600+300mg.44768.77568	
Precio EEUU por capsula	24.83
Regalia base 5%	1.242 por cápsula
Ingreso promedio Ecuador (siguiendo indicador Banco Mundial 2011) http://datos.bancomundial.org/indicador/NY.GDP.PCAP.CD	4569
Ingreso promedio EEUU (siguiendo indicador Banco Mundial 2011) http://datos.bancomundial.org/indicador/NY.GDP.PCAP.CD	48442
Proporcion ingreso promedio Ecuador a EEUU	4569/48442= 0.094318979
Regalia a grada	1.242 x 0.094318979= 0.117 por capsula

IEPI

Las regalías aquí establecidas a favor de GLAXO GROUP LIMITED se fijarán obteniendo el 5% como regalía base, respecto del precio de venta de cada unidad de LAMIVUDINA + ABACAVIR 300 mg + 600 mg, a este valor se lo multiplicará por el coeficiente de proporción de ingreso promedio de Ecuador a EEUU.

Dicho coeficiente se obtiene mediante la división realizada entre el ingreso promedio de Ecuador (PIB Ecuador por persona) y el ingreso promedio de EEUU (PIB EEUU por persona), para efectos de proporcionalidad y homogeneidad en esta resolución se considerará como fuente de estos datos la información proporcionada por el Banco Mundial, a través de su enlace web http://datos.bancomundial.org/indicador/NY.GDP.PCAP.CD

Respecto a la oferta del precio del medicamento, se deja constancia que el solicitante, esto es ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. libre y voluntariamente conforme su escrito de fecha 15 de junio de 2012 para el producto LAMIVUDINA + ABACAVIR 300 mg + 600 mg fijo como límite el precio referencial de la tableta en 6.11 USD.

El incumplimiento en los valores ofertados por estos productos es decir la venta de los productos con precios que superen los valores aquí establecidos libre y voluntariamente por ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. ocasionarán la revocatoria de la licencia de manera inmediata, generándose para ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. las responsabilidades que por este incumplimiento tenga previsto la normativa aplicable.

El plazo para el pago de la compensación económica será el 31 de diciembre de cada año, con un periodo de gracia de hasta máximo 30 días contados desde el vencimiento del plazo inicial. En caso de no cumplir su obligación con el licenciante este podrá requerir a la Dirección Nacional de Propiedad Industrial la inmediata revocación de la licencia. El licenciatario deberá llevar archivos y libros de contabilidad precisos y exactos de forma tal que se recojan todos los datos razonablemente necesarios para el cálculo y verificación de las cantidades pagaderas en concepto de liquidaciones de compensación económica.

4.- De acuerdo a lo establecido en el artículo 5 número 10-04 P-IEPI denominado "*Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos*", y de conformidad con su petición inicial contenida en la solicitud de fecha 15 de junio de 2012, la licencia se concede exclusivamente para su fabricación, oferta en venta, venta o uso del producto, importación para uso de estos fines, y destinada al Uso Público No Comercial, para consumo nacional en territorio ecuatoriano en los términos referidos en la petición realizada. La violación a este requisito, implicará la revocatoria mediante resolución de la licencia, previa prueba del licenciante o de cualquier tercero perjudicado.

5.- No exclusividad, de acuerdo con el artículo 11 del "*Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos*" en concordancia con el artículo 68 literal a) de la Decisión 486, la presente Licencia Obligatoria no tendrá carácter exclusivo. El licenciatario no podrá ceder los derechos originados por la licencia obligatoria salvo con aquella parte de la empresa o del activo intangible que disfrute de ellos. La concesión de licencias obligatorias no [illegible] el derecho del titular de seguir explotando la patente;

6.- Revocatoria de la licencia obligatoria, de conformidad con el artículo 14 del "Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos", la Dirección Nacional de Propiedad Industrial, de oficio o a petición de parte, podrá revocar la licencia obligatoria cuando las circunstancias que dieron origen a la licencia hayan desaparecido y no sea probable que vuelva a surgir, o cuando el licenciatario cumpla las disposiciones previstas en la resolución que otorga la licencia obligatoria;

7.- Marginación de la licencia obligatoria, ordénese la marginación de la presente Licencia Obligatoria a favor de ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A. a la Unidad de Gestión de Patentes y/o Modificaciones al registro y/o Secretaría General, de la patente signada con el número de trámite No. SP-98-2505, cuya denominación es "Una nueva sal", cuyo titular es GLAXO GROUP LIMITED, con título No. PI-08-1913, vigente hasta el 14 de mayo del 2018

La impugnación de la licencia obligatoria no impedirá el ejercicio de los derechos que corresponda al licenciatario en virtud de ella, ni ejercerá ninguna influencia en los plazos que estuviere corriendo. La interposición de cualquier recurso no impedirá al titular de la patente percibir, entre tanto, la compensación económica determinada por la DNPI en la parte no reclamada.

El presente acto administrativo es susceptible de los recursos establecidos en el Art. 357 de la Ley de Propiedad Intelectual: Recurso de Reposición ante esta misma Dirección en el término de quince días; Recurso de Apelación para ante el Comité de Propiedad Intelectual, en el término de quince días; Recurso de Revisión para ante el Comité de Propiedad Intelectual, en los plazos establecidos en el Estatuto del Régimen Jurídico y Administrativo de la Función Ejecutiva; o por vía jurisdiccional ante uno de los Tribunales Distritales de lo Contencioso Administrativo. **NOTIFÍQUESE.-**

Ab. Juan Fernando Salazar
DIRECTOR NACIONAL DE PROPIEDAD INDUSTRIAL

Razón: La providencia que antecede se notificó a la compañía GLAXO GROUP LIMITED, por intermedio de su apoderada, Bustamante & Bustamante Patentes y Marcas Cía. Ltda. en la casilla IEPI No. 11 de la ciudad de Quito, y, a la compañía ACROMAX LABORATORIO QUIMICO FARMACEUTICO S.A., por intermedio de su apoderada Abg. María José Zurita Luna, en la casilla IEPI No. 5 de la Subdirección regional del IEPI en Guayaquil, dado en la ciudad de Quito D.M., el día
Certifico.-

Ab. Nathalie Rostan Palacios
SECRETARIA GENERAL (S)

专利、强制许可和药品可及性：最新经验

专利药的高价问题已成为发展中国家主[redacted]别是在世界贸易组织(WTO)的TRIPS协议生效之[redacted]定了严格的专利规范。然而，尽管TRIPS协议对[redacted]可一些符合公共利益的例外和灵活性。

本文探讨TRIPS协议许可的灵活性--强制许可、政府使用和平行进口--发展中国家可以实施这些灵活性排除药品专利并提供更多可负担的药物。

最新是一些国家（包括泰国、马来西亚、印度尼西亚、巴西、津巴布韦、加纳、美国、意大利、印度和厄瓜多尔等）运用强制许可、政府使用命令或其他灵活性方式生产和进口廉价的专利药品仿制药。

但是，作者警告说，新一轮的发达国家与发展中国家双边自由贸易协定(FTAs) 通过施加比TRIPS协议更为严格的专利标准大大削弱了这些灵活性。如果任其发展，有着“TRIPS-plus”条款的自由贸易协定趋向可能影响整个发展中国家贫困病人对基本药物的获取。

MARTIN KHOR是南方中心的总执行长和第三世界网络的前执行董事。其中，南方中心是发展中国家建立的政府间国际组织，现有51个成员国。他是一名经济学家，曾在剑桥大学学习，发表和出版了关于贸易、发展和环境问题的文章和书籍。

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由第三世界网络出版，从第三世界视角对知识产权保护进行批判性分析，特别关注世界贸易组织（WTO）的《与贸易有关的知识产权协议》（TRIPS协议）及其对发展中国家的影响。

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